In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-850V

(to be published)

A.Y., *by his parents and natural guardians,* J.Y. *and* S.Y.,	*	Chief Special Master Corcoran
Petitioners,	*	Filed: June 26, 2020
v.	*	Varicella vaccine; Viral latency; Reactivation; *Althen* prong three; Chickenpox; Behavioral problems; Significant aggravation
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Renee Gentry, Vaccine Injury Litigation Clinic, George Washington University Law School, Washington, DC, Petitioner.

Jennifer Reynaud, U.S. Dep't of Justice, Washington, DC, Respondent.

ENTITLEMENT DECISION[1]

On June 22, 2017, J.Y. and S.Y. filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program")[2] alleging that their son, A.Y., experienced the reactivation of a varicella virus in 2014 or 2015 that was made possible by a varicella vaccine he was administered seven-plus years prior, in November 2007. Petition (ECF

[1] This Decision will be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen 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 current 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. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

No. 1) at 1. This case was one of three filed on behalf of A.Y. and his siblings— triplets born November 14, 2006. *Id.*[3] All of the claims have been consolidated into this matter. This Petition alleges a causation-in-fact, non-Table claim, and also a significant aggravation claim.

Petitioners' claim is quite novel. It depends on a finding that a vaccine-caused injury could, in effect, occur *years* after the vaccine's administration—something no petitioner before has succeeded in establishing (in a non-Table context), and which somewhat flies in the face of the legal view (implicit in the timeframe prong of the Federal Circuit's causation test set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (2005)) that *some* timeframes are simply too long to establish entitlement to damages, even taking into account the leniency of the Vaccine Program. But the claim proceeds from reliable science about the capacity of a wild virus varicella infection to be latent for long periods of time. I have therefore carefully considered Petitioners' arguments, along with the expert/treater support offered for them and A.Y.'s medical history.

For the reasons set forth below, I deny entitlement in this case. Even if it is true that the wild varicella *virus* can reactivate years after an infection, Petitioners have failed to offer sufficient reliable evidence that the *varicella vaccine* could do the same. Moreover, A.Y.'s medical history is so replete with complications, pre-onset symptoms, and controversial treatments that could have contributed to his symptoms that it is impossible to (a) deem the vaccine causal of his post-reactivation symptoms (which have not been persuasively demonstrated to be distinct from those he experienced before the alleged reactivation), or (b) conclude that he did in fact experience reactivation in the first place. I also do not find that a significant aggravation claim has been successfully established.

I. Factual Background

The following is obtained from the medical record filed in this case plus the pleadings. As Respondent noted in his Rule 4(c) Report, however, the records Petitioners initially filed were extremely disorganized and appeared to be incomplete, with numerous gaps, and such deficiencies have never been completely cured despite opportunity to do so.[4]

[3] In early 2018, two additional petitions were filed, one for each of A.Y.'s siblings, alleging an injury from the same varicella vaccine. *See* Order Granting Mot. to Consolidate at 1, filed Jan. 4, 2018 (ECF No. 16).

[4] Respondent noted the existence of several (more than a dozen) incomplete records in his Rule 4(c) Report. *See, e.g.*, Respondent's 4(c) Rep. at 2–3 n.1–n.5, filed Nov. 15, 2018 (ECF No. 29). In order to address these documentary deficiencies, I granted Petitioners' 2019 Motion to Strike Exhibits 1–18 (all of the records filed in the case at that time time). Order to Strike, filed Feb. 19, 2019 (ECF No. 31), at 1. Even after refiling, however, some exhibits *still* had more than twice the number of pages as their erroneous counterparts, and other deficiencies remain (for example, Petitioners' Exhibit 24 is missing page 4). It is therefore impossible to conclude that the records are now complete.

A.Y.'s Early Life and 2007 Receipt of the Varicella Vaccine

A.Y. is the eldest of triplets, born prematurely (after 33 weeks gestation) on November 14, 2006. Ex. 24 at 38–54. He spent more than a month after birth in a neonatal intensive care unit, during which time he experienced reflux and was seen by a gastroenterologist. *Id*. at 48–49. The medical records do not thereafter reveal any significant concerns over the ensuing year for A.Y. or his two siblings. In November 2007, at his one-year well-child visit, A.Y. was administered the varicella zoster virus ("VZV") vaccine. *Id.* at 5. There is no indication in the filed medical records that he experienced any immediate symptoms in association with receipt of this vaccine.

Developmental Problems and Medical Issues Predating Alleged Reactivation

It is undisputed in this case that A.Y. and his siblings have experienced developmental delays, and even received autism diagnoses, although Petitioners (at least expressly) do not allege these to be vaccine-related injuries. Nevertheless, A.Y.'s medical history in the wake of discovery of these developmental problems—and in particular the treatments he received—is highly relevant to the injuries that Petitioners do associate herein with the varicella vaccine.

Petitioners were concerned that A.Y. was possibly developmentally delayed as early as the end of 2007/start of 2008, when he was first evaluated and started on speech therapy, followed by occupational therapy. Ex. 21 at 750. He and his siblings were later examined for developmental delays by Helping Hands Clinic in San Antonio, Texas on June 25, 2008, when they were about 19 months old. Ex. 32 at 1–4. The medical evaluator noted that A.Y. had been receiving Early Childhood Intervention services through Easter Seals Rehabilitation since December 2007. *Id*. at 3. A.Y. was formally diagnosed with autism in November 2009, when he was three (and thus two years post-vaccination). Ex. 29 at 5–8.[5]

During the same general time period, Petitioners also began raising issues with A.Y.'s pediatric treaters about his gastrointestinal health. When A.Y. was 18 months old (late spring 2008), his pediatrician noted that A.Y. was eating some solids but not meat, cheese, or yogurt. Ex. 24 at 11. The following year, A.Y. was evaluated by Ricki G. Robinson, M.D. (one of the treaters offering an opinion in this case) at the Descanso Medical Center for Development and Learning in LaCanada, California, a medical facility specializing in treatment of autism spectrum disorders ("ASD") and related conditions. Ex. 27 at 2–40. Dr. Robinson noted, *inter alia*, that A.Y. had generally experienced difficulties with eating. *Id.* He was subsequently tested for celiac disease in May 2009, but the results were negative, and his IgG antibody levels were within the

[5] This exhibit appears to be missing the last page.

normal range. Ex. 24 at 33–37.

It was at this point in A.Y.'s life that treatments for his disparate health issues began to converge—especially to the extent that certain treaters sought out by Petitioners were proponents of the concept that autism is linked to gastrointestinal problems (and hence improvement of the latter is a means of treating the former). Thus, in early 2010, Petitioners took A.Y. to pediatrician Jerrold Kartzinel, M.D., at Kartzinel Wellness Center in Orlando, Florida.[6] Ex. 21 at 750–53.[7] In a medical history found in the records for this visit, Dr. Kartzinel recounted that A.Y. had experienced partial epilepsy/seizure (although the medical record does not corroborate this)[8] and chronic constipation with "mushy stools," and Dr. Kartzinel included in the differential diagnosis encephalopathy, metabolism disorder, immune mechanism disorder, and abnormal feces. *Id*. at 752. Dr. Kartzinel also surmised that certain of A.Y.'s behavioral problems were likely attributable to a falling accident he experienced at the age of two (even though the record shows concerns for A.Y.'s development overall beginning almost a year before). *Id*. at 634.

By the summer of 2010, A.Y. (now three and one-half years old) was being "followed by multiple physicians because of gastrointestinal issues," as well as by Drs. Robinson and Kartzinel for his developmental problems. Ex. 19 at 3. That July, Dr. Kartzinel wrote a "to whom it may concern" letter (perhaps to guide other treaters or assist Petitioners in obtaining other dispensations needed to help care for him) asserting that A.Y. had been diagnosed with epilepsy, gastroesophageal reflux, encephalopathy, metabolism disorder, sleep disorder, immune mechanism disorder, and abnormal feces. Ex. 21 at 427. He recommended a "special diet" for A.Y. and included a lengthy list of prohibited food items. *Id.*

Treatment 2010–14

In the ensuing four-plus years before the alleged onset of reactivated varicella virus, A.Y. received a dizzying number of treatments and medications. Among other things, Dr.

[6] Dr. Kartzinel is a proponent of autism therapies and treatments that are not well accepted by the medical community. It has been noted in other Vaccine Program cases that he was associated with "DAN!" ("Defeat Autism Now"), an entity that has proposed such clinically-unsubstantiated treatments. *Holt v. Sec'y of Health & Human Servs.*, No. 05-0136V, 2015 WL 4381588, at *10 ns.41, 43(Fed. Cl. Spec. Mstr. June 24, 2015). He also co-authored a book on autism with television celebrity Jenny McCarthy. Jenny McCarthy & Jerry Kartzinel, *Healing and Preventing Autism: A Complete Guide* (2010).

[7] It appears that Exhibit 21 is incomplete and is missing at least two pages. *See* Ex. 3 at 753. Internal pagination states "page 326 of 328" but the exhibit ends here. *Id.*

[8] In the summer of 2009, a 24-hour EEG performed on A.Y. showed some secondary generalized epileptic discharges in sleep, for which A.Y. was prescribed medication. Ex. 27 at 91, 93. In August of that same year, however, he underwent a brain MRI that produced normal results. Ex. 30 at 53. A.Y. otherwise does not appear to have formally been diagnosed with epilepsy or seizure activity.

Kartzinel recommended a "mito cocktail" of supplements to treat a purported mitochondrial/energy processing disorder. *See, e.g.*, Ex. 21 at 706. A.Y. also was prescribed a variety of other medications, including (a) three 90-day courses of Acyclovir/Valtrex (an anti-viral drug used primarily for treatment of herpes and chickenpox)[9] (Ex. 21 at 490, 698, 724, 744); (b) antibiotics and antifungal medication for "mouthing" (*Id.* at 724, 726–27, 740); (c) leucovorin/folinic acid, most commonly used to treat chemotherapy side effects or folate deficiencies (*Id.* at 704–11); (d) Gabapentin/Neurontin (nerve pain medication and anti-conversant) (*Id.* at 722); (e) an attention-deficit/hyperactivity disorder medication (*Id.* at 362); and (f) a medication used to treat dementia and Alzheimer's disease (*Id.* at 648). In addition, A.Y. received hyperbaric oxygen therapy, a questionably-effective therapy often employed in the treatment of autism. *Id.* at 724.[10] And in the late fall of 2013, A.Y. received stem cell therapy as well. *Id.* at 608.

In the midst of receiving such wide-ranging medical interventions, A.Y. was diagnosed in September 2013 with a "cycle of abdominal pain." Ex. 20 at 1; Ex. 21 at 616. By this time, S.Y. had noted to certain treaters that A.Y. received a very limited diet, and although he was gaining weight had grown no taller over the prior year. Ex. 20 at 1.[11] His abdominal pain episodes had purportedly responded well to certain over-the-counter treatments, but continued to exist off and on, varying in their severity. *See e.g.*, Ex. 21 at 430, 566–68, 582, 594–96, 604–10. Nevertheless, a colonoscopy performed on October 22, 2013, produced normal results, except for some patchy erythema in A.Y.'s small intestine mucosa, and proof of esophageal reflux. Ex. 30 at 29–36.

The records filed for 2014 also evidence the variety of treatments Petitioners pursued for A.Y. Thus, A.Y. received immunoglobulin and steroidal treatments for his abdominal issues in the early winter of 2014. Ex. 21 at 588–90. He also continued to undergo stem cell treatments, with some records suggesting some of the treatments were administered in Panama. *Id.* at 301, 304, 209. In addition, a February 2014 record contains Dr. Kartzinel's notation that A.Y. had recently been exposed to measles, causing him to express the concern that this might result in the "reactivating" of the herpes virus, although the records do not explain how this would have occurred

[9] The record provides no explanation for why chickenpox would be a concern in a child who had already received the varicella vaccine. However, Acyclovir/Valtrex are also used to treat herpes (the symptoms of which can be similar to chickenpox), and there is record evidence that treaters like Dr. Kartzinel had concerns that A.Y. might be at risk for an HHV6/herpes infection. Ex. 21 at 582.

[10] *Anderson v. Sec'y of Health & Human Servs*., No. 02-1314V, 2016 WL 825628, at *6 n.10 (Fed. Cl. Nov. 1, 2016), *mot. for review den'd,* 131 Fed. Cl. (2017), *aff'd*, 717 F. App'x 1009 (Fed. Cir. 2018).

[11] This record, like others, appears incomplete. Thus, a record from May 27, 2015, states that the date of A.Y.'s last visit was April 23, 2015, even though no record of that visit appears to have been filed. Ex. 20 at 21.

(or when A.Y. was believed to have first been exposed to the herpes virus). *Id.* at 329. There is no other evidence in the actual contemporaneous medical record that A.Y. experienced any rashes that might reflect a recurrent varicella infection in 2014 – and thus no record evidence substantiating the contention that A.Y.'s reactivation could have begun in the summer of 2014.

Alleged Onset of Reactivated Chickenpox/Varicella

The first evidence from the record of a possible varicella-associated rash comes from January 2015. At that time, A.Y. (now eight years old) saw his pediatrician, and S.Y. reported that A.Y. had just developed a rash, starting on his neck and spreading throughout his body. Ex. 30 at 4. A.Y. did not have a fever, but "fluid filled lesions" were observed along with skin erythema. *Id.* His pediatrician now diagnosed A.Y. with "possible atypical varicella" and prescribed the same anti-viral medication, Acyclovir, that the record reveals A.Y. had been receiving in years past—in the absence of a chickenpox/varicella diagnosis. *Id.*

There is no record of any follow-up visit with the pediatrician who proposed this varicella diagnosis. However, a few days later, on January 8, 2015, it appears that S.Y. had an on-line discussion with Dr. Kartzinel, reporting to him that the rash/chickenpox-appearing lesions had "almost cleared up. ([W.Y.] and [J.Y.] both had this, AJ too, did well) Never caused itching or discomfort." Ex. 21 at 548. The waning of the observed rash is again reported in a subsequent record from January 12, 2015. *Id*. at 546 ("[a]cylovir . . . much better, lesions cleared up").[12] No other records thereafter support the propriety of the January 2015 diagnosis, or reflect other testing performed to confirm it.

Subsequent Treatments Received by A.Y.

The medical records for the remainder of 2015 and forward that have been filed in this case demonstrate the same broad attempts to treat A.Y.'s developmental and other symptoms with a wide array of therapies and medications. But these records are highly inconsistent in their discussion, or even mention, of A.Y.'s purported varicella reactivation, and also are unsupportive of Petitioners' contentions that certain of A.Y.'s pre-reactivation symptoms now worsened.

In the second half of 2015, for example, A.Y. saw a gastroenterologist—Arthur Krigsman, M.D.[13]—and the records from the initial visits described A.Y.'s overall history, but do not mention

[12] These records also confirm that A.Y.'s behavior issues predated the onset of the observed rash, since there is reference in them to treatment of aggressive and rage-filled behavior in 2014, as well as to the fact that at this time A.Y. was "still" prone to such outbursts. Ex. 21 at 548.

[13] Dr. Krigsman was one of many experts who more than ten years ago offered testimony in the Omnibus Autism Proceeding (the "OAP")—a proceeding which combined into three test cases thousands of claims asserting similar

any rash or chickenpox lesions from the prior January. Ex. 33 at 14–35. Dr. Kartinzel was consulted again about A.Y. in November 2015, at which time S.Y. reported that A.Y. had been experiencing stomach pain and also "the beginnings of a chick pox type rash," for which she had (again) administered Acyclovir. Ex. 21 at 498–99.

That same November, at a pre-endoscopy/colonoscopy physical, S.Y. repeated the claim that A.Y. was experiencing chickenpox lesions, adding that he had experienced five such episodes over the prior eleven months, but that they had responded well to the Acyclovir treatments. Ex. 30 at 62. These records do not corroborate the underlying facts reported in this medical history, however. Dr. Krigsman was responsible for performing the colonoscopy/endoscopy on A.Y. that November 2015. Ex. 21 at 172–79. The pathology report revealed no diagnostic abnormalities, but Dr. Krigsman nevertheless diagnosed A.Y. with autism spectrum disorder (ASD)-associated enteritis (a diagnosis he has maintained is legitimate despite ample authority to the contrary).[14] Ex. 21 at 104–10, 172.

Around this time, one of Petitioners' three experts offering opinions in this matter, Anne Gershon, M.D. (a researcher and professor of pediatrics at Columbia University College of Physicians and Surgeons), apparently was provided access to the biopsy results, and later (as discussed below) prepared a report on them—although she did *not* do so at the time, and no other records from Dr. Gershon or this research facility have been filed. Ex. 34 at 1. But Dr. Gershon did subsequently represent in a December 2015 email to Dr. Krigsman that she had "found RNA transcripts of 3 [varicella] genes (#62, 63, 67) in the intestinal specimens that were in RNA later . . . Finding those transcripts indicated an intestinal infection of the mucosa." Ex. 21 at 492. Dr. Gershon proposed in response that A.Y. should receive Valacyclovir to "relieve [A.Y.'s] abdominal pain," and Dr. Kartzinel agreed to prescribe it. *Id.* at 493. It was also suggested that A.Y. be taken to see allergist/immunologist Raffi Tachdjian, M.D. *Id.* at 494.

The very next month, in late December 2015, A.Y. was seen by Dr. Tachdjian – who made findings that undermined some of the assumptions about A.Y.'s alleged varicella reactivation. Ex. 26 at 3. Dr. Tachdjian described photos of A.Y.'s rash as appearing "viral but not that of classic

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causation theories involving the alleged capacity for certain vaccines to cause ASDs. None of these cases succeeded. *See, e.g.*, *Cedillo v. Sec'y of Health & Human Servs*., No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review den'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010). Dr. Krigsman specifically testified that the measles virus, derived from a child's MMR vaccine, could linger in the intestinal tissue of autistic children, causing chronic gastric inflammatory distress. *Cedillo*, 2009 WL 331968, at *103–04. However, Dr. Krigsman was deemed to possess significant deficiencies in his professional credentials and experience. *Id.* at *105-06. In addition, the theory he offered was characterized as "quite unpersuasive" (*Id.* at *107), because (a) it relied on questionable testing results, (b) it embraced the "autistic enterocolitis" theory that discredited medical expert Dr. Andrew Wakefield had espoused, and (c) it did not take into account the actual relevant medical history pertaining to the purportedly injured child (*Id.* at *108–14).

[14] *See, e.g.*, *Cedillo,* 2009 WL 331968, at *108–14.

varicella or HSV." *Id*. But he also noted that A.Y. had tested *negative* for varicella IgG antibodies, suggesting that A.Y. had not had prior exposure in spite of Dr. Gershon's findings, and also that A.Y.'s herpes antibody levels were normal. *Id*. Dr. Tachdjian ultimately prescribed IVIG therapy to address "poor antibody function." *Id*.

In 2016, Petitioners continued to seek advice from the same overall constellation of treaters, none of whom diverged particularly from previously-expressed views. In February 2016, for example, A.Y. again saw Dr. Krigsman, who reiterated his opinion that A.Y. suffered from ASD-associated enteritis, acknowledging Dr. Gershon's other findings with respect to varicella reactivation although not seeming to rely on them for his opinion. Ex. 21 at 28; *see also* Ex. 33 at 25.

Dr. Tachdjian, by contrast, appeared to believe that the proper diagnosis for A.Y. had not been determined, and wrote a letter to the Undiagnosed Disease Network in August 2016 to that end. Ex. 26 at 5–7. He acknowledged that A.Y. had experienced chickenpox-like marks, but that IVIG treatment caused them to subside. *Id.* The letter also maintained, however, that a saliva test performed in February 2016 was positive for varicella zoster. *Id.* at 6. Indeed, Dr. Tachdjian proposed that A.Y. suffered from a "recurrent Varicella infection" in his intestines, asserting that Dr. Gershon's findings corroborated this. *Id.* at 5. He added that the purported infection was the cause of "chronic pain" that A.Y. experienced but which could be alleviated by some of the antiviral treatments he received, although he could not explain the reason why the infection could not be suppressed by A.Y.'s immune system. *Id.*

Earlier that year, on February 3, 2016, A.Y. saw pediatric infectious disease specialist Paul Krogstad, M.D. Ex. 35 at 1–6. He took note of the finding from Dr. Gershon of varicella zoster virus replication, along with repeated rashes in 2015 generally. *Id.* at 1. However, although Dr. Krogstad expressed the belief that the rashes were "compatible with varicella," he added that their apparent rapid resolution after Acyclovir treatment suggested the need to consider other possible causes, including viral exanthemas or enterovirus infections. *Id*. at 5.

Petitioners have filed no other subsequent records bearing on A.Y.'s purported injury.

II. Expert and Treater Opinions

A. Dr. Robinson

As noted above, Dr. Robinson (a clinical pediatric professor) has been treating A.Y. in connection with his autism diagnosis for more than ten years. She prepared a three-page letter-report in support of Petitioners' claim. Report, dated March 25, 2019, filed as Ex. 39 (ECF No.

34-4) ("Robinson Rep.").

Dr. Robinson earned her M.D. from the University of Southern California in 1973. Robinson CV at 1, filed May 13, 2019 (ECF No. 37-3). She served as Chief Pediatric Resident at Children's Hospital Los Angeles in 1976 and is board certified in pediatrics. *Id.* In 1988 she earned her Masters in Public Health from the University at Berkeley School of Public Health. *Id.* She has been in private practice for nearly 40 years and currently serves as the co-director of Descanso Medical Center for Development and learning in La Canada, California. *Id.* Most of her expertise is focused on autism and helping children with developmental delays. *See id.*

Dr. Robinson's report largely summarizes A.Y.'s medical history from 2009 (when she first diagnosed him with an ASD) through February 2019, the month before her report's preparation, based on her personal knowledge from contact with him. Robinson Rep. at 2–3. Although she does opine that A.Y. has experienced a "marked change" in his health (as particularly reflected in worsened behavioral changes) since his abdominal pain purportedly increased, and although she temporally associates these changes with the alleged varicella reactivation, her opinion of an association does not arise from direct knowledge pertaining to *how* a vaccine might result in viral reactivation. Indeed, she assumes reactivation was "proven" by Dr. Gershon's purported discovery in November 2015 from A.Y.'s biopsy of the same varicella strain as that he received in 2007. *Id.* at 1–2. Her opinion is thus significantly dependent on Dr. Gershon's (and thus relies upon its scientific reliability).

More importantly, Dr. Robinson's report acknowledges that A.Y.'s behavioral changes, presumably attributable to severe abdominal pain exacerbated by the varicella reactivation, may actually have *predated* the January 2015 onset that the medical records support (since that is the best evidence of *when* A.Y. first displayed what could be chickenpox lesions). Thus, Dr. Robinson states that "*beginning in the fall 2014* but definitely after the January 2015, VZV outbreak," A.Y. experienced a progressive change in behavioral symptoms. Robinson Rep. at 3 (emphasis added). She otherwise, however, recounts instances of behavioral problems in 2015 and later, after the first record-substantiated manifestations of a purported varicella reactivation. *Id.* at 2–3.

B. Dr. Richard A. Honaker

Dr. Honaker, a family practice physician, provided for this case a medical records chronology as well as a brief, three-page report. *See* Letter, dated March 22, 2019, filed as Ex. 40 (ECF No. 34-5) ("Honaker Chronology"); Report, dated March 22, 2019, filed as Ex. 43 (ECF No. 34-8) ("Honaker Rep."). Dr. Honaker had no direct treatment involvement with A.Y.,

unlike Drs. Robinson and Gershon.

Dr. Honaker earned his M.D. from the University of Virginia in 1977. Honaker CV at 1, filed on Mar. 28, 2019 (ECF No. 34-9). After graduating from medical school, he completed his internship at Mt. Carmel Medical Center in 1978 to 1979. *Id.* Then, from 1982 to 1984 he was a family practice resident at Parkland Memorial Hospital/St. Paul Medical Center and the University of Texas Health Science Center/Children's Medical Center. *Id.* He has been in private practice since 1984 and is board certified in Family medicine. *Id.* at 1–2.

Dr. Honaker's records chronology largely tracks the medical history recounted above, and appends some items from the filed records to it, such as A.Y.'s vaccination history, or literature relevant to Dr. Gershon's opinion. It repeats the contention that A.Y. experienced some kind of chickenpox-like rash or lesions as early as June 2014, although it does not provide a record citation for its assertion (and my own review of the record finds no substantiation for onset beginning that early). Honaker Chronology at 1. Dr. Honaker also acknowledges (consistent with my own review of the record) that the disorganized and incomplete state of the filed medical records made it impossible for him to prevent "inaccuracies and errors" in his summary. *Id.* at 2.

The expert opinion offered by Dr. Honaker is set forth in his report. He reiterates his prior chronology and then, while allowing that the evidence presented in this case is "somewhat ambiguous and uncertain," goes on to provide an opinion based on his review of the record. Honaker Rep. at 2. Dr. Honaker asserts that there is a temporally-broad period in which the record suggests reactivation may have occurred, measuring the period from the fall of 2013 (the time of A.Y.'s normal intestinal biopsy) to January 2015 (although he again repeats without record citation the assertion that there was evidence of a rash in June 2014). *Id.* He then maintains that A.Y. (a) likely experienced reactivation of the virus in January 2015, as corroborated by Dr. Gershon's fall 2015 findings, and (b) suffered exacerbation of his GI-related pain and behavioral issues thereafter. *Id.*

Dr. Honaker is frank in acknowledging the limitations of his opinion. He admits that he lacks specialization in the medical or scientific areas put into dispute in this case, other than his family practice exposure to administering vaccinations or treating chickenpox. Honaker Rep. at 2. He recommends contacting other professionals to conduct a "multidisciplinary interaction" amongst them to ascertain the issues in this case, and refers to an article attached to his chronology that was authored and offered in this case by Dr. Gershon. *Id.* at 3.

C. Dr. Gershon

Anne Gershon, M.D., a researcher and professor of pediatrics at Columbia University

College of Physicians and Surgeons, was the third and final expert/treater consulted for an opinion in this case. In addition to her report, she prepared a document in 2017 (several months after the claim's filing) that references the biopsy results from A.Y.'s 2015 colonoscopy, and her opinion relies on this 2017 document. Report, filed as Ex. 38 on March 28, 2019 (ECF No. 34-3) ("Gershon Rep."); "Molecular Test Report for Research Patient #57," dated November 9, 2017, re-filed as Ex. 34 on February 20, 2019 (ECF No. 33-8) (the "Molecular Test Report").

Dr. Gershon earned her M.D. at Cornell medical school. Gershon CV at 1, filed on May 13, 2019 (ECF No. 37-2). After graduating from medical school, beginning in 1986, she became a professor of pediatrics at Columbia University College of Physicians and Surgeons. *Id.* There she researched "epidemiology, diagnosis, immunology, latency, prevention, and treatment of varicella and zoster. *Id.* Since then she has researched VZV, Zoster, and latency and reactivation throughout her career. *See id.* at 1–2; *see also* Gershon Rep. at 1. She currently practices medicine at New York-Presbyterian Morgan Stanley Children's Hospital and is board certified in Pediatrics and Pediatric Infectious Disease. *Id.* at 2, 6.

Dr. Gershon's report begins by observing that the VZV vaccine contains attenuated components of the live varicella virus. Gershon Rep. at 2. She then notes that it is medically understood that the wild varicella virus can stay latent for long periods of time, 'hiding" in the sensory neurons, but can then be reactivated to cause infection. *Id.* Her theory therefore supposes that the live viral components of the vaccine could similarly become latent in the same manner as a wild virus infection.

Dr. Gershon does not offer any literature to bulwark this contention, but appended to *Dr. Honaker's* medical history chronology was an article co-authored by Dr. Gershon and her husband, Dr. Michael Gershon, discussing the latency concept. Michael and Anne Gershon, *Varicella-Zoster Virus and the Enteric Nervous System,* 218 J. Infect. Diseases, Supp. 2:S113–19 (2018), attached to Honaker Chronology at 6–12 (the "Gershon Article").[15] The Gershon Article is primarily focused on an animal study its authors performed that demonstrated the varicella virus could also be latent in autonomic nervous system neurons, and in particular in the enteric nervous system (which governs the function of the gastrointestinal tract), thereby on reactivation causing some GI-oriented conditions. Gershon Article at S113. Although the Gershon Article did not specifically analyze the impact of vaccination versus wild infection in understanding enteric reactivation, or the nature of the injuries a vaccine-related reactivation would produce in any sense, it does mention that vaccination has been found to be capable of latency and reactivation, even though the vaccine was administered in the periphery, through viremia (in which the viral particles contained in the vaccine would access the blood stream,

[15] Notably, Dr. Michael Gershon himself offered an opinion *against* Dr. Krigsman's theory about ASD-associated gastrointestinal illness in the OAP cases. *See, e.g.*, *Cedillo,* 2009 WL 331968, at *105.

allowing them transport throughout the body). *Id.* at S113–14. The literature cited in the Gershon Article for these propositions has not been filed in this case, however.

Dr. Gershon went on in her report to consider A.Y.'s history, including the role she played in his treatment in 2015. She notes that A.Y. and his siblings received the VZV vaccine in 2007 and never experienced clinical chickenpox (thus establishing no evidence of a prior varicella infection that could be reactivated). However, after reviewing in 2015 the results of the biopsy performed that same year by Dr. Krigsman, Dr. Gershon discovered that A.Y. was experiencing an "active" varicella infection of a strain consistent with that contained in the vaccine administered eight years before, but inconsistent with the wild virus strain, and that the infection persisted into 2016 despite treatment, as evidenced by saliva tests (the evidence of which does not appear to have been filed in this case). Gershon Rep. at 2. She then maintains that beginning in 2015 A.Y. started to experience severe abdominal pain at the same time he was displaying chickenpox-like rashes, events that in her view reflected the existence of varicella reactivation. *Id.* She went on to predict that this reactivation would persist in A.Y.'s life, and that treatment would be somewhat ineffective in controlling it, due to A.Y.'s sensitivities to the side effects of antiviral medications. *Id.* at 2–3.

No other literature or evidence was filed in connection with Dr. Gershon's report. However, as noted above Dr. Gershon did file the Molecular Test Report—a one-page document dated November 9, 2017 (nearly two years after A.Y.'s biopsy) and signed by Dr. Gershon and a Jason Chen, Ph.D., identified as a research scientist at Columbia University's College of Physicians and Surgeons. The Molecular Test Report refers to review of the intestinal biopsy for a "Patient #57" that was reviewed in November 2015. There is no way, however, to tell from the document's face when it was created or who "Patient #57" was, although it presumably refers to A.Y.'s biopsy, which the record confirms Dr. Gershon in fact reviewed in 2015. The document references the following finding: "VZV ORFs 62, 63, 67, 68 were each positive by nested PCR." Molecular Test Report at 1. This is likely the finding referenced in Dr. Gershon's Report, although it is only partially corroborated by the record, which records Dr. Gershon informing A.Y.'s treaters only that RNA transcripts for three VZV genes were identified. Ex. 21 at 492, 495–96. No backup materials relating to this testing has been filed, further increasing the difficulty of confirming the accuracy of such representations.

III. Procedural History

As noted, this claim was initiated in 2017, and originally assigned to former Special Master Millman. Two more claims were filed for A.Y.'s two siblings in early 2018, but assigned

to me.[16] Before completion of the filing of medical records, however, the present claim was also assigned to me, and I subsequently ordered the three related claims consolidated into one. Order, dated January 4, 2018 (ECF No. 16).

Respondent's Rule 4(c) Report was not filed until November 2018, and contested the propriety of compensation. ECF No. 29. Given the extreme novelty of the claim, and concerns I had about its viability based on a preliminary view of the record,[17] I thereafter issued a show cause order requiring Petitioners to demonstrate why the claim should not be dismissed. Docket entry dated November 28, 2018. In response, Petitioners filed a brief defending their claim (with respect solely to the first A.Y.-filed petition) on May 13, 2019 (ECF No. 38) ("Br."). Respondent reacted to my Order and requested dismissal in a pleading filed September 11, 2019 (ECF No. 41) ("Opp."). Petitioners thereafter offered a reply brief on December 12, 2019 (ECF No. 44) ("Reply").

IV. Parties' Respective Arguments

Petitioners maintain that the VZV vaccine A.Y. received in 2007 caused the virus components it contained to stay latent in his body for years (just as it is known the wild virus can do). Br. at 5. It can then be reactivated "at any time" thereafter, and in doing so could produce chickenpox symptoms, and also cause or exacerbate abdominal pain and developmental problems. Reply at 1. For evidence that the vaccine did cause A.Y.'s post-2015 symptoms, Petitioners point to the November 2015 intestinal biopsy review by Dr. Gershon, which purported to find evidence of the varicella virus that was consistent with the vaccine's components. Br. at 5–6. And the timeframe for reactivation was medically acceptable, with A.Y. experiencing chickenpox-like rashes beginning at least in January 2015, followed by bouts of severe abdominal pain and aggressive behavior associated with his other developmental problems. *Id.*

Respondent countered these points, and argued for dismissal of the claim. He referenced

[16] *See W.Y. v. Sec'y of Health & Human Servs.*, No. 18-11V (filed January 2, 2018) ("Matter II"), and *A.Y. v. Sec'y of Health & Human Servs.*, No. 18-12V (filed January 2, 2018) ("Matter III"). Matter II was filed on behalf of W.Y., and alleged (unlike with respect to A.Y.) that W.Y.'s chickenpox/varicella reactivation symptoms only began in January 2015, and also seems to argue that W.Y.'s developmental problems generally *are* vaccine-caused. In Matter III, Petitioners asserted that a different sibling, but also with the initials A.Y., experienced reactivation with onset in June 2015. In both more-recent filings, however, Petitioners maintained the siblings had (similar to this case) tested positive for a reactivated vaccine-contained varicella strain.

[17] Earlier in the case's life I also expressed some concerns about whether the claim was timely under the Act's three-year/thirty-six month limitations period, since the vaccination had occurred over *seven years* before onset—but because Vaccine Act claims only run from first manifestation of symptoms (whether or not they are so understood) allegedly due to a vaccine, and since this claim was filed in 2017 based on symptoms that are alleged to have arisen no earlier than summer 2014, I have treated it as timely for statute of limitations purposes.

A.Y.'s overall record, and the extent to which it reveals the myriad number of treatments and ASD-oriented therapies, some of which do not find widespread acceptance in the medical community. Opp. at 4–5. He also noted that the purported chickenpox rash appears to have cleared up right away and/or responded to medication (the same medication that A.Y. received multiple times between the date of vaccination and his symptoms manifestation), thus raising questions about whether in fact A.Y. did experience varicella reactivation. And he emphasized that although Petitioners have denied asserting A.Y.'s autism was vaccine-caused, they *do* seem to associate his purported varicella reactivation with worsening of autism-related symptoms, such as poor behavioral control (evidence of which *predated* the most likely onset of January 2015), even though that kind of claim has repeatedly been rejected in the Program. *Id.* at 5–6. Indeed, it is Respondent's view that Petitioners have not clearly delineated what A.Y.'s injury actually is. *Id.* at 6–7.

Based on the above, Respondent asserts that Petitioners cannot preponderantly establish entitlement in this case. Petitioners, he argues, have not demonstrated that the vial components of the VZV vaccine could remain latent for the amount of time at issue herein to cause injury—or that in fact it did so to A.Y. in this case. In the latter regard, Respondent notes that the evidence offered from Dr. Gershon purportedly corroborating the latent, post-vaccination varicella infection is not supported by the record, which only includes Dr. Gershon's one-page Molecular Test Report without corroborative back-up information. Opp. at 7–8. The contention that A.Y. even had a varicella infection as of January 2015 is not itself record-supported. He also points out that there is significant record evidence that certain of A.Y.'s purported symptoms, such as declining behavioral control, predated vaccination. *Id.* at 7–9. And Respondent questions the value of Drs. Robinson and Honaker's reports otherwise. *Id.* at 8.

On reply, Petitioners contend that A.Y.'s vaccine injury was recurrent chickenpox symptoms—including severe abdominal pain, rash, and pain related anxiety—and these symptoms began "as early as June 24, 2014 and certainly by January 2, 2015." Reply at 5. Petitioners also maintained that the varicella vaccine would remain latent in the body for years and then reactivate causing the constellation of A.Y.'s symptoms. *Id.* at 6. They also argued that Drs. Gershon and Robinson's reports should be afforded greater weight because of their position as treaters. *Id.* at 6–7 (citing *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006)). Petitioners conclude that based on "the medical documentation of Drs. Robinson and Gershon [] A.Y. has met the preponderant standard of substantial contribution to significant aggravation of the claimant's complex medical issues like GI pain and behavioral issues secondary to vaccine-strain VZV reactivation . . . ." *Id.* at 7.

V. Applicable Law

A. *Standards for Vaccine Claims*

To receive compensation in the Vaccine Program, a petitioner must prove that: (1) they suffered an injury falling within the Vaccine Injury Table (i.e., a "Table Injury"); or (2) they suffered an injury actually caused by a vaccine (i.e., 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 & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano*, 440 F.3d at 1320. In this case, Petitioners do not assert a Table claim.

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) (explaining that mere conjecture or speculation is insufficient under a preponderance standard). On one hand, proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). But on the other hand, 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 & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human 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 and is discussed in turn along with the parties' arguments and my findings.

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 & Human 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. This standard was recently clarified by the Federal Circuit. *See Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1359–60 (Fed. Cir. 2019) (correct standard for *Althen* prong one is "reputable," and "sound and reliable," not a "lower reasonable standard" (internal quotations omitted)).

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 & Human 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. This is consistent with the petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).[18]

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 & Human 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 & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views 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 & Human 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 also be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians'

[18] Although there has been some confusion in the past as to whether the first *Althen* prong is *itself* subject to a preponderant standard, ample controlling authority stands for the more straightforward proposition that the first *Althen* prong is subject to a preponderance standard. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010).

conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human 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, 356–57 (2011), *aff'd without opinion*, 475 F. App'x. 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 & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide 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 & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11–355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Standards Applicable to Significant Aggravation Claim*

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 & Human 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 & Human 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.

Subsumed within the *Loving* analysis is the requirement to evaluate the likely natural course of an injured party's preexisting disease, in order to determine whether the vaccine made the petitioner worse than he would have been but for the vaccination. *Locane v. Sec'y of Health & Human Servs.,* 685 F.3d 1375, 1381–82 (Fed. Cir. 2012) (upholding special master's determination that petitioner had failed to carry her burden of proof in establishing that her preexisting injury was worsened by the relevant vaccine); *Hennessey v. Sec'y of Health & Human Servs.*, No. 01-190V, 2009 WL 1709053, at *41–42 (Fed. Cl. Spec. Mstr. May 29, 2009), *mot. for review denied*, 91 Fed. Cl. 126 (2010). The critical point of examination is thus "whether the change for the worse in [petitioner's] clinical presentation was aggravation or a natural progression" of the underlying condition. *Hennessey,* 2009 WL 1709053, at *42.[19] The Federal Circuit has upheld the determinations of special masters that worsening was not demonstrated in connection with establishing a petitioner's overall preponderant burden of proof for a non-Table causation-in-fact claim. *See, e.g., Snyder/Harris v. Sec'y of Health & Human Servs.*, 553 F. Appx. 994, 999–1000 (Fed. Cir. 2014); *Locane,* 685 F.3d at 1381–82.[20]

C. *Law Governing Analysis of Fact Evidence*

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 & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford

[19] The legislative history of the Vaccine Act strongly supports interpreting "significant aggravation" as requiring a claimant to establish that a vaccine rendered a preexisting condition qualitatively worse than it would have been otherwise—not simply that the affected individual experienced a post-vaccination symptom that contrasts with the individual's comparatively better pre-vaccination health. *See* H.R. Rep. No. 99-908, at 15 (1986) ("This [significant aggravation] provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), *but is meant to encompass serious deterioration* (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis" (emphasis added)).

[20] This is consistent with the fact (well recognized by controlling precedent) that evidence of "worsening" relevant to Respondent's alternative cause burden may reasonably by evaluated by a special master in determining the success of a petitioner's prima facie showing. *Snyder/Harris*, 553 F. Appx. at 1000 ("'[N]o evidence should be embargoed from the special master's consideration simply because it is also relevant to another inquiry under the statute.'" (*quoting Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1380 (Fed. Cir. 2012))); *see also de Bazan* at 1353 ("[t]he government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief.").

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).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human 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 & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people 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 & Human Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human 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 & Human Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally 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 & Human 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, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human 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 & Human*

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 & Human 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 & Human 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.

D. *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 & Human 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 & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human 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).

However, in the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings—e.g., 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 & Human 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 & Human 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 & Human 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 & Human 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").

E. *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 in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioners' case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human 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 & Human 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").

F. *Consideration of Prior Vaccine Program Decisions*

In reaching a decision in this case, I have considered other decisions issued by special masters involving similar injuries, vaccines, or circumstances. I also reference some of those cases in this Decision, in an effort to establish common themes, as well as demonstrate how prior determinations impact my thinking on the present case.

There is no error in doing so. It is certainly correct that prior decision in different cases do not *control* the outcome herein.[21] *Boatmon v. Sec'y of Health & Human Servs.,* 941 F.3d 1351, 1358-59 (Fed. Cir. 2019); *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). Thus, the fact that another special master reasonably determined *elsewhere*, on the basis of facts not in evidence in this case, that preponderant evidence supported the conclusion that vaccine X caused petitioner's injury Y does not compel me to reach the same conclusion in *this* case. Different actions present different background medical histories, different experts, and different items of medical literature, and therefore can reasonably result in contrary determinations.

However, it is *equally* the case that special masters reasonably draw upon their experience in resolving Vaccine Act claims. *Doe v. Sec'y of Health & Human Servs.,* 76 Fed. Cl. 328, 338-39 (2007) ("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the *expertise and experience to know the type of information that is most probative of a claim*") (emphasis added). They would thus be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions. This is especially so given that special masters not only routinely hear from the same experts in comparable cases, but are also repeatedly offered the *same* items of medical literature regarding certain common causation theories. It defies reason and logic to obligate special masters to "reinvent the wheel," so to speak, in each new case before them, paying no heed at all to how their colleagues past and present have addressed similar causation theories or fact patterns. It is for this reason that prior decisions can have high persuasive value—and why special masters often explain how a new determination relates to such past decisions.[22] Even if the Federal Circuit does not *require* special masters to distinguish other relevant cases (*Boatmon,* 941

[21] By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014). Special masters are also bound within a specific case by determinations made by judges of the Court of Federal Claims after a motion for review is resolved.

[22] Consideration of prior determinations is a two-way street that does not only inure to the benefit of one party. Thus, I would likely take into account the numerous decisions finding no association between vaccination and autism when confronted with a new claim asserting autism as an injury, and have informed such claimants early in the life of their case that the claim was not viable for just that reason. But I would *also* deem a non-Table claim asserting GBS after the flu vaccine as not requiring extensive proof on *Althen* prong one "can cause" matters, for the simple reason that the Program has repeatedly litigated the issue in favor of petitioners.

F.3d at 1358), it is still *wise* to do so.

G. *Disposition of Case Without Hearing*

I am resolving this claim (one of three included in the consolidated matters) on the papers, rather than by holding a hearing. 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 & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Human 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 & Human 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 & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Varicella Reactivation and Relevant Varicella Vaccine Cases

Because the capacity of the varicella virus to become latent then reactivate is squarely placed into issue by Petitioners' causation theory, some brief discussion of what is scientifically and medically known about the mechanisms involved in this process is warranted.

A VZV infection (which is often termed "chickenpox") is caused by varicella – a highly contagious virus that impacts almost every person before adulthood. *See Atlas of Pediatric Physical Diagnosis* 444 (5th ed. 2007). Its initial symptoms, usually occurring after a 10–21 day incubation period, include fever, malaise and the itchy rash for which it is best known. *Id.* A VZV infection is usually self-limiting and mild, although severe and potentially-fatal complications may arise, such as secondary bacterial infections or neurologic impacts (encephalitis). *Id.* Varicella is especially dangerous to children and the immune-compromised. One form, "breakthrough" varicella, occurs in person who received the varicella vaccine but subsequently (42 days or more post-vaccination) incur a wild virus infection, and features a slightly different kind of presenting rash. *Infectious Diseases (Varicella-Zoster Virus)* in Nelson Textbook of Pediatrics 1581 (R. Kliegman et al., 20th ed. 2016) ("Nelson").

A varicella infection is commonly diagnosed from clinical indicia, such as the presence of the rash commonly associated with it. Nelson at 1584. However, some laboratory testing can also

confirm its presence. Evaluation of the virus's presence from direct testing of skin lesions/vesicles is most common, although strain identification can also assist in distinguishing the wild virus from vaccine-associated strains. *Id.* It is commonly treated with the antiviral drug Acyclovir, although the drug's cost, coupled with the low risk of complications, often result in it not being routinely prescribed. *Id.* It does not appear that gastrointestinal pain or sequelae are an understood feature or complication of a varicella infection. *Id.* at 1579-80.

One feature of VZV that distinguishes it from other viral infections is its capacity for latency and subsequent reactivation. *Pearson v. Sec'y of Health & Human Servs.,* No. 16-9V, 2019 WL 3852633, at *15 (Fed. Cl. Spec. Mstr. 2019) ("varicella zoster reactivation is a relatively common ailment—approximately 1 million new cases are diagnosed annually in the United States, and 90% of these patients are immunocompetent"). After exposure to the virus in childhood, the immune system of most individuals is successful in eliminating it, but it often remains dormant/latent in two parts of the central nervous system: the ganglia adjacent to the spinal cord or base of the skull. Phillip S. LaRussa & Mona Marin, *Textbook of Pediatrics: Chapter 253 Varicella-Zoster Virus* 1579 (20th ed. 2016). Thereafter, the virus can reactivate in adulthood, causing a varicella zoster infection, or "shingles," which is characterized by a painful localized rash. *Id.* Although shingles usually resolves in a few weeks, it can have associated secondary symptoms, or lead in some cases to ongoing nerve pain or neuralgia. *Pearson,* 2019 WL 3852633, at *15. Only those who previously were infected with VZV can experience shingles, and it most commonly afflicts those over 50 (and thus the virus's latency can be decades-long).

It remains unknown to medical science *why* the VZV remains latent for such lengthy periods of time. However, it has been determined that during dormancy, infected nerve cells continue to manufacture viral proteins, suggesting that rather than true latency, the dormant period might better be characterized as a chronic, if extremely low-level, active infection. Bjørn Grinde, *Herpesviruses: Latency and Reactivation—Viral Strategies and Host Response*, J. of Oral Microbiology (2013) (available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3809354/). The immune system otherwise suppresses this ongoing, sub-clinical infectious process—consistent with the fact that shingles is more common in those whose immune systems are compromised (whether due to aging, receipt of medical treatments known to be immunosuppressive, or psychologic stress). *Shingles*, Mayo Clinic (June 10, 2020, 5:17pm), https://www.mayoclinic.org/diseases-conditions/shingles/symptoms-causes/syc-20353054. Regardless, it is clear that shingles does *not* constitute merely a second "round" of chickenpox.

Here, Petitioners maintain that a varicella vaccine introduced VZV strains that (consistent with what is known about the wild virus's reactivation and expression as shingles) self-reactivated in a consistent manner, manifesting as chickenpox and triggering some other secondary symptoms. I have found no causation-in-fact decisions in which a petitioner established injury due to a reactivated varicella infection introduced by prior varicella vaccination. At most, petitioners have

successfully demonstrated that the varicella vaccine *directly* caused an injury—including a subsequent varicella infection.[23] *See, e.g.*, *Hayes v. Sec'y of Health & Human Servs*., No. 18-804V, 2019 WL 3821992 (Fed. Cl. May 14, 2019) (varicella vaccine conceded by Respondent to have caused varicella infection)*; Haigler v. Sec'y of Health & Human Servs.,* No. 11-508V, 2013 WL 5428103 (Fed. Cl. Spec. Mstr. Sept. 5, 2013) (varicella vaccine caused encephalopathy); *Casey v. Sec'y of Health & Human Servs*., No. 97-612V, 2005 WL 3597263 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) (varicella vaccine caused encephalomyeloradiculo-neuropathy). But in such cases, onset from vaccination to injury was a matter of a few weeks—not seven years, as alleged here. *See, e.g.*, *Hayes*, 2019 WL 3821992 (onset of infection two to three weeks post-vaccination);[24] *Haigler*, 2013 WL 5428103, at *17–18 (onset of encephalopathy within two weeks of receipt of varicella vaccine); *Casey*, 2005 WL 3597263, at *1–2 (onset of neurologic injuries began four to six weeks post-vaccination).

There are, however, two Table claim variants recognizing varicella reactivation after vaccination as a compensable injury (although Petitioners do not advance a Table claim). *See* 42 C.F.R. § 100.3(a)(X)(C). The Table claim version most relevant to this case[25] is titled "disseminated varicella vaccine-strain viral disease," and requires the claimant to prove *either* "varicella illness that involves the skin beyond the dermatome in which the vaccination was given," or "disease caused by vaccine-strain varicella in another organ." 42 C.F.R. § 100.3(c)(11). Significantly, there is no Table timeframe in which post-vaccination onset for reactivation must be established—although if the claimant cannot demonstrate the presence of a vaccine-strain of the varicella, then onset must be established to have occurred within 7–42 days of vaccination. *Id.*[26]

I am aware of only two published decisions in which a claimant received compensation for a Table varicella reactivation claim of the aforementioned kind. But in both instances, onset occurred *far sooner* than alleged herein. *See, e.g.*, *Hayes v. Sec'y of Health & Human Servs.*, No.

[23] In comparison, Petitioners have been denied entitlement where Respondent was able to establish that a reactivated varicella infection was a more likely alternative cause of the claimed injury than a subsequent different vaccine—thus acknowledging the injuries that reactivation could cause. *See, e.g.*, *Dunn v. Sec'y of Health & Human Servs*., No. 16-1506V, 2020 WL 1243237 (Fed. Cl. Spec. Mstr. Feb. 19, 2020) (Tdap vaccine not responsible for petitioner's meningoencephalitis, but instead Respondent established preponderantly that varicella zoster virus reactivation was causal).

[24] The ruling on entitlement in *Hayes* does not set forth such facts, which are instead found in Respondent's Rule 4(c) Report conceding entitlement. *See Hayes* Rule 4(c) Report, dated May 9, 2019 (ECF No. 24).

[25] The other varicella reactivation Table claim involves injury manifesting as shingles, which does not capture what A.Y. is alleged to have experienced. 42 C.F.R. § 100.3(c)(12).

[26] In addition, if testing reveals the presence of a wild-type viral strain or some other non-vaccine strain, then the Table claim fails entirely. 42 C.F.R. § 100.3(c)(11).

18-804V, 2019 WL 3821992 (Fed. Cl. Spec. Mstr. May 14, 2019) (Table injury conceded where petitioner experienced chickenpox 18 days after receipt of varicella vaccination); *Garner v. Sec'y of Health & Human Servs.*, No. 17-1166V, 2018 WL 1835549 (Fed. Cl. Spec. Mstr. Mar. 5, 2018) (Respondent conceded varicella reactivation Table claim based on evidence of injured child's strokes and hemiparalysis with onset within ten days of vaccination). And neither of these cases involved the kind of sequelae (GI-related pain and behavioral outbursts, associated with that pain or not) alleged herein.

II. Petitioners Have Not Established that A.Y. Experienced Chickenpox in January 2015 That was Attributable to Reactivation of the Varicella Strains Contained in the Vaccine He Received in 2007

As in many Vaccine Program cases, identifying whether the "injury" alleged actually occurred is critical to this claim's resolution. *Broekelschen*, 618 F.3d at 1346. Although Petitioners point to certain injurious secondary harms (A.Y.'s worsened behavioral conduct, abdominal pain, and skin rashes), all are linked to a purported varicella reactivation starting in January 2015 and manifesting as chickenpox,[27] that was in turn attributable to a vaccine received seven or eight years before. The evidence in this case does not preponderate in favor of such a finding.

Petitioners' injury contentions arise from accepted medical science concerning wild varicella infections generally, and their capacity for latency and subsequent reactivation. But Petitioners go a step further: they argue that the varicella vaccine *itself* could introduce a sufficient amount of the virus to be latent for years and then subsequently "reactivate" (here, activate for the first time), thereafter having the same injurious effect as a first-time wild virus infection. Although the mechanism for how latency in this context occurs remain poorly understood, I credit the reliability of Petitioners' general contention that after an initial infection (typically manifesting as chickenpox), the varicella virus can lay dormant (or at least act in a low-grade/chronic infectious manner) for long periods of time. Reliable evidence has also been offered that viral strains contained in the varicella vaccine might have a similar latency effect (although it is hardly established herein that receipt of a viral strain via vaccination is comparable to a wild virus infection). Indeed, other claimants have obtained entitlement based upon the argument that a varicella vaccine "caused" subsequent varicella-like symptoms (although not in a years-long timeframe, and thus not after the lengthy dormancy presented in this case). *See, e.g.*, *Hayes*, 2019 WL 3821992. The fact that a Table claim exists also suggests that reliable scientific evidence

[27] The record in this case *does not* support Petitioners' alternative contention that A.Y. experienced such symptoms in June 2014, and therefore I date onset as of no earlier than January 2015, since there is *some* record support for that determination. In addition, the evidence offered in this case regarding varicella reactivation after latency supports the conclusion that A.Y.'s January 2015 symptoms were characteristic of chickenpox—not shingles. Children do not commonly experience shingles, moreover, and Petitioners do not allege A.Y.'s presenting symptoms constituted shingles. *See generally* Pet. at 1–3; Opp.; Reply.

substantiates *some* possibility of post-vaccination reactivation (although little such evidence was offered in this case).

But it has *not* been preponderantly established in this case that A.Y. likely had *any* active varicella infection as of January 2015, manifesting as chickenpox—whether from a new, wild virus infection or reactivation of the viral strains introduced by vaccine. At best, the medical record contains evidence of a rash or marks suggesting that A.Y. *might* have had chickenpox at that time, but the record does not confirm the initial, equivocal diagnosis, nor were these marks accompanied by any of the other presenting indicia of a varicella infection, such as fever. In addition, the record includes statements from S.Y. that the marks rapidly cleared up (which she attributes to antiviral medications A.Y. was administered even *before* he purportedly showed viral reactivation at this time). Thus, even if these symptoms were initial evidence of a "new" varicella infection, the record establishes that they dissipated in days (thus *also* allowing for the conclusion that the injury's severity did not meet the Act's six-month requirement). Section 11(c)(1)(D)(i). Indeed, later, close-in-time intervening medical records from 2015 make no mention of any bout with chickenpox earlier that year. And although there are records from the fall of 2015 suggesting, without explanation, recurrences (which are *not* consistent with a varicella infection's usual course in any event), these have not been corroborated.

Furthermore—and unlike cases in which an injured party manifested symptoms associated with varicella reactivation, like neuralgias or encephalopathies—A.Y. did *not* display symptoms after his purported 2015 winter manifestation of a rash that could be so defined. It has not been established herein that recurrent abdominal pain of the kind A.Y. is purported to have experienced is a varicella hallmark or anticipated sequela. The record also reveals that A.Y. received antiviral medications intended to treat a varicella infection, like Acyclovir, throughout his life, suggesting a prior concern for earlier infections (which if also attributed to vaccine reactivation would not be a basis for recovery under the Act's three-year limitations period). No blood testing, antibody findings, or other serologic evidence has been offered to corroborate that a varicella infection existed as of the winter of 2015. And I find significant Dr. Tachdjian's treating opinion, rendered in December 2015, that certain test results, such as antibody findings, were *not* consistent with the conclusion that A.Y. had experienced a varicella infection. Ex. 26 at 3.

In addition, the record does not preponderantly establish that the chickenpox-like skin symptoms A.Y. is alleged to have experienced in 2015 were likely attributable to a reactivation of the varicella virus components of the vaccine A.Y. received seven-plus years before. The strongest evidence for reactivation is found in Dr. Gershon's late-2015 biopsy review, in which she reports finding varicella vaccine strains from A.Y.'s intestinal biopsy. But these findings suffer from reliability problems. For one, the report setting forth this conclusion appears to have been created *two years after* Dr. Gershon's findings (although the contemporaneous record itself from 2015 does corroborate that Dr. Gershon considered the biopsy as alleged). More importantly, no

substantive back-up data for the findings has been filed, making it impossible to confirm the accuracy of these representations. And Petitioners have offered no other evidence that would corroborate their assumption that evidence of the presence of vaccine-strain varicella virus in the gut makes it more likely that A.Y.'s January 2015 symptoms were associated with reactivation.

Thus, the assertion that the viral strains found by Dr. Gershon match the vaccine's components, but not the wild virus itself, has not been substantiated in the record filed in this case (which as noted above has numerous holes and gaps). And even if the existence of strains associated with vaccination had been preponderantly established, Petitioners have not *also* established that reactivation is the most likely explanation for A.Y.'s symptoms months before – as opposed to an intervening wild virus infection.

III. Petitioners did not Preponderantly Support Their Contention that the Timeframe From Vaccination to Purported Reactivation Onset was Medically Acceptable

Even if my prior analysis is incorrect, the third *Althen* prong[28] proves an insurmountable roadblock to the success of Petitioners' claim.

As the Court of Federal Claims has recognized, a timeframe from vaccination to injury that is not medically acceptable—whether too short or too long—eliminates the possibility of a favorable entitlement award, *even where* the first two causation prongs can be established. *See de Bazan*, 539 F.3d at 1352. And the degree to which the proposed timeframe "misses the mark" matters – especially if onset occurs well after receipt of the vaccine. As Judge Bruggink observed in *Hennessey v. Sec'y of Health & Human Servs*., 91 Fed. Cl. 126 (2010), there are some proposed timeframes that are so long that all concepts of medical reasonableness and acceptability fly out the window. *Hennessey*, 91 Fed. Cl. at 142 ("this theory accounts for symptoms which do not occur until years after vaccination, exacerbated by some other environmental trigger. . . [under this theory] it would be virtually impossible to determine that the vaccine, and not some other environmental condition, was the original triggering event"). As a result, a too-long timeframe from vaccination to injury threatens to "define away" the third prong, by permitting recovery for *any* post-vaccination harm, no matter how remote in time. *Id.*

[28] I do not address the other *Althen* prongs in detail herein, but note that, with respect to the second "did cause" prong, my injury finding precludes a determination that the varicella vaccine likely caused harm via reactivation, since I have not found that A.Y. likely had chickenpox in January 2015, and/or that the symptoms he had at that time can reliably be attributed to vaccine strain varicella reactivation. The evidence that varicella strains in the varicella vaccine *could* reactivate is somewhat stronger, although it has not been preponderantly shown that they would manifest as a first-time varicella infection. And in any event, because Petitioners cannot demonstrate that seven years post-vaccination is a medically acceptable timeframe for reactivation of vaccine-introduced viral strains, it does not matter that some reliable evidence (largely not filed herein but derived from my review of other cases) supports the "can cause" *Althen* prong.

This is such a case. Admittedly, the Gershon Article (which I note was not even contained in Dr. Gershon's submissions, although filed with Dr. Honaker's report and filings) supports the contention that the varicella vaccine may have viral reactivation effects comparable to the wild virus, although none of the references cited in the Gershon Article for this proposition were themselves filed.[29] But Petitioners have offered no evidence establishing *what period of time* from vaccination to reactivation would be medically acceptable, making it extremely difficult for me to find that more than seven years (the relevant timeframe in this case) is acceptable. Indeed, the varicella vaccine (which includes a live but attenuated varicella virus strain) is intended to be *less* virulent than the wild virus,[30] so it cannot simply be assumed that the same latency periods apply to both. *See, e.g.*, *Varivax,* FDA (Oct. 19, 2018), https://www.fda.gov/vaccines-blood-biologics/vaccines/varivax. (package insert for varicella vaccine describing contents). The timeframe is so great in this case that the possibility of an intervening wild virus infection cannot be discounted (even in the presence of the biopsy findings).[31] It cannot simply be assumed that *any* post-vaccination evidence of a varicella infection after receipt of the vaccine is due to reactivation.

Petitioners' timeframe argument also suffers when A.Y.'s individual circumstances are factored into the consideration. In this case, Petitioners allege a seven-plus year gap from vaccination to clinical manifestation of reactivation. During this period, A.Y. received a dizzying plethora of treatments for his ASD, and was repeatedly said to be experiencing a wide variety of symptoms—including autism-related developmental problems and gastrointestinal symptoms, sometimes manifesting as abdominal pain. *See, e.g.*, Ex. 20 at 1–2. Some of these could well have been stimulated by the intrusive treatments he received from 2007 to 2015 (many of which lack general medical community or ASD treater acceptance). But whatever their cause, it cannot on this record be concluded that A.Y. experienced *no* possible intervening triggers for either a first-

[29] My cursory review of the three most relevant footnoted, but unfiled, articles, however, does not identify strong support for Dr. Gershon's assertions. Gershon Article at S119, n.31–33. For example, the article referenced in support of the possibility of viremia to explain how vaccine-containing viral components could cause subsequent disease later is a single-patient case study nearly 30 years old, and involves an unquestionably immune-compromised child. I. Kamiya et al., *Viremic Phase in Leukemic Child After Live Varicella Vaccination*, 89 Pediatrics 147 (1992). Another more recent article's abstract reveals its authors' conclusion that varicella vaccination *reduces* the likelihood of viral reactivation in later life. S. Weinmann et al., *Incidence and Clinical Characteristics of Herpes Zoster Among Children in the Varicella Vaccine Era*, 208 J. Infectious Disease 1859 (2013). None appear to stand strongly for the proposition that a vaccine administered years before could have the same reactivation potential as the wild virus.

[30] An attenuated vaccine is "a vaccine prepared from live microorganisms or viruses cultured under adverse conditions leading to loss of their virulence but retention of their ability to induce protective immunity." Attenuated Vaccine, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=116493.

[31] I also note that Petitioners have *assumed* that the findings of what are represented to be vaccine-strain varicella virus in A.Y's intestinal biopsy must explain the rash symptoms he began manifesting several month before – but without demonstrating (whether from persuasive expert opinion or other reliable scientific and medical evidence) why such evidence makes it preponderantly likely that the two are connected.

time infection or vaccine reactivation (assuming it did occur) that could not also explain his purported symptoms from 2015 onward.

At bottom, the timeframe in question (from vaccination to onset) is so lengthy that absent very reliable scientific evidence linking the varicella *vaccine* with reactivation years later, I cannot find that its medical acceptability has been preponderantly established. This case stands in marked contrast to even the few published Table claim cases directly involving vaccine-strain varicella reactivation, none of which featured timeframes exceeding *three weeks* post-vaccination. *Hayes*, 2019 WL 3821992; *Garner*, 2018 WL 1835549. While it may be somewhat plausible that a varicella vaccine *could* plant the seed for a viral reactivation years later, a claimant hoping to succeed in establishing entitlement based on such a novel, years-long timeframe would have to do a far better job substantiating that assertion than Petitioners have achieved in this case.

IV. Petitioners Did Not Establish Their Significant Aggravation Claim

It is somewhat difficult to discern the exact nature of Petitioners' significant aggravation claim, but it appears that they maintain that A.Y.'s alleged reactivation of varicella in January 2015 was followed by "significantly more prominent GI symptoms and behavioral issues." Reply at 4. But too many of the *Loving* prongs have not been preponderantly established to find in favor of Petitioners on this alternative claim.[32]

First, many of the secondary symptoms that Petitioners claim were aggravated by A.Y.'s purported reactivated, vaccine-caused infection were either inadequately substantiated by the medical record, or cannot be concluded to have become worse post-reactivation. Thus, there is ample medical record evidence that A.Y. experienced abdominal pain well before onset of the alleged reactivation in January 2015**.** *See, e.g.*, Ex 21 at 606–07 (noting "at least one pain episode a day" and "patchy erythema" in A.Y.'s small intestine on November 4, 2013), 616 (noting A.Y. had a "cycle of abdominal pain" on September 10, 2013); *see also* Ex. 21 at 596–97, and Ex. 26 at 6 ("at approximately 4 years of age, Andrew started experiencing significant aggression which was later determined to be from his GI pain"). But the medical record does not establish that these symptoms in fact *worsened* after January 2015, despite some conclusory assertions to the contrary by some of Petitioners' experts. *See, e.g.*, Ex. 21 at 548. Indeed, I cannot ascertain from this somewhat-incomplete record how to compare A.Y.'s pre versus post-reactivation health overall. As a result, *Loving* prongs two and three have not been preponderantly established. The record is simply too full of evidence of ongoing medical problems to possibly tease out how any of A.Y.'s

[32] Although *Loving* focuses on comparing the injured party's condition before and after vaccination, this claim compares A.Y.'s condition pre and post-*reactivation*, with virtually none of his purported aggravated symptoms having existed before receipt of the varicella vaccine in 2007 (when A.Y. was just a year old). But because Vaccine Program claims only *begin* as of onset - and thus any significant aggravation claim accrues not on the literal date of vaccination, but some time thereafter, even if by only a few days—I do not find that this distinction alone rules out a significant aggravation claim herein.

purported post-reactivation harms were appreciably different from his condition before January 2015.

Second, Petitioners have not demonstrated how a reactivated varicella infection could even cause worsening of the kind alleged in this case. The primary symptoms alleged to have worsened are abdominal pain and behavioral problems—*neither* of which have been shown to be medically associated with a first-time varicella infection. Indeed, they are not even the kinds of symptoms *known* to be potential (and dangerous) secondary effects of a varicella infection, like the kinds of serious neurologic complications that have been deemed compensable injuries attributable to varicella. *See, e.g.*, *Haigler,* 2013 WL 5428103 (varicella vaccine caused encephalopathy); *Casey*, 2005 WL 3597263 (varicella vaccine caused encephalomyeloradiculo-neuropathy). Rather, it seems to have been the assumption of certain of A.Y.'s treaters that abdominal pain could be associated with an existing varicella infection in the gut – an assumption that the record does not bear out in the least.[33] Thus, *Loving* prong four has also not been satisfied.

Third, there is ample unrebutted record evidence that some of A.Y.'s GI symptoms could just as likely be attributable to the panoply of treatments he received. Petitioners adopted a blunderbuss approach in seeking to treat A.Y.'s autism and other conditions that certain of their treaters, like Dr. Krigsman, have associated with ASD, like gastrointestinal problems (even though these associations have been questioned from a scientific/medical standpoint). *See Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968, at *1, *102, *108–09 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (challenging the scientific reliability of Dr. Krigsman's (ASD)-associated enteritis theory). Given the variety of medications A.Y. received and dietary changes mandated for him, it cannot be discounted that some GI symptoms he experienced could be so attributed (and Petitioners certainly did not prove the contrary). Petitioners therefore cannot preponderantly establish that *any* GI problems, whether before or after purported onset of A.Y.'s chickenpox symptoms, were more likely relevant to that injury versus the nature of the treatments he received.

Claims that A.Y.'s behavioral problems worsened due to varicella reactivation from his 2007 vaccination are even less tenable. Dr. Robinson, Petitioners' autism treating expert, has admitted that A.Y. displayed increasing behavioral problems *before* he first manifested a skin rash in early 2015. Robinson Rep. at 3. As with A.Y.'s GI complaints, I do not discern in this record that A.Y.'s behavioral issues were in fact worse after purported reactivation; rather, the overall record suggests that his behavioral problems were more likely attributable to his ASD, and that they waxed and waned independent of his alleged chickenpox symptoms. Even more compellingly, there is *no* support in the Program for the conclusion that *any* vaccine could, directly or otherwise, cause or exacerbate existing ASD-related symptoms, let alone VZV through

[33] This assumption also seems congruent with the view of treaters like Dr. Krigsman about the existence of ASD-associated enteritis—a diagnosis that is not medically accepted, as discussed below and above.

reactivation. *See Pope v. Sec'y of Health & Human Servs.*, No. 14-078V, 2017 WL 2460503, at *21–23 (Fed. Cl. Spec. Mstr. May 1, 2017) (discussing lack of support for claims that ASD can be significantly aggravated by a vaccine). Indeed, there is no reliable scientific or medical evidence offered in this case that a *first-time* varicella infection could make existing ASD-associated behavioral problems worse (beyond the logical conclusion that pain or other symptoms associated with the reactivation might be difficult for an ASD-diagnosed child to process and cope with).

Overall, the medical records filed in this case do not establish a marked difference between A.Y.'s condition pre or post-alleged reactivation, nor have Petitioners established that (a) varicella reactivation *could* worsen GI and ASD-associated behavioral problems or (b) that it did so here. Thus, the significant aggravation claim has not been preponderantly established.

V. This Case was Properly Resolved Without a Trial

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 explain my reasoning nevertheless.

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 (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*. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to decide a matter, 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—although they should only so act if a party has been given the proper "full and fair" chance to prove their claim.

In this case, no hearing was required to resolve fairly the present claim. My decision to dismiss this case turns primarily on Petitioners' inability to show that a seven-year latency for varicella reactivation after vaccination was medically acceptable, or that such reactivation could cause the symptoms alleged. Although Petitioner offered three expert opinions, only one (Dr. Gershon's) even went to the issue of causation, and it was facially insubstantial (and said nothing about the *Althen* prong three issue). Giving that opinion as much credit as possible, as I have attempted to do, was not enough to carry the day for Petitioners—and no hearing would have made a different result possible. Petitioners have had ample opportunity to substantiate the claim—and were given adequate warnings by me that issues raised by the lengthy gap between vaccination and onset would determine the claim's outcome.

The fact that Respondent offered no experts of his own did not mandate a hearing, or require me to give Petitioners' arguments (and/or the testimony of their experts) a credence that they did not merit. I am *never* obligated to accept blindly the say-so of any expert, pro or con, and I was able to draw on my experience in Vaccine Act cases generally (as well as consider some relevant prior cases discussed above) to ascertain the significant limitations undermining the expert opinions. Petitioners simply have not proven that a seven-year lag is medically acceptable. None of the expert support offered for their claim was especially robust - one expert (Dr. Robinson) conceded a central weakness in the significant aggravation claim, one (Dr. Honaker) disavowed his expertise to opine in the case, and the third (Dr. Gershon) did not bother to offer the medical literature most supportive of her theory. The evidence simply did not even rise to a threshold preponderant showing that would suggest the need for Respondent expert input.

Admittedly, this case presented some novel issues (here relating to onset and post-vaccination timeframe)—but that fact alone also does not necessitate a hearing, as the Federal Circuit has observed. *See D'Tiole v. Sec'y of Health & Human Servs.*, 726 F. App'x 809, 812 (Fed. Cir. 2018). I was able to evaluate the preponderant strength of Petitioners' claim by review of the record, the briefs, and the expert reports filed, and could fairly ascertain issues with the claim even though it advanced a theory that has not been evaluated extensively in past written decisions. It is conceivable that a claimant armed with better literature shining a light on the latency potential of varicella strains in the varicella vaccine, or more persuasive experts with the background needed to offer a reliable and persuasive opinion, could mount a case that would raise enough fact questions to mandate a hearing—but not so here.[34] Petitioners were given a fair chance to substantiate their claim.

CONCLUSION

Petitioners base their claim on a single, reasonably-sound medical concept specific to the wild varicella virus and its scientifically-demonstrated capacity for latency and reactivation. Some reliable evidence supports the contention that the viral strains in the varicella vaccine may also have latency potential. But Petitioners have not offered sufficient reliable support in this case for me to determine (in ruling on a non-Table claim) that the attenuated viral strains of this vaccine could activate *years later* in the pathologic manner alleged. Moreover, the facts relevant to A.Y.'s

[34] My determination not to hold a hearing was also influenced in minor part by the undeniable fact that this case presents circumstances common to many other ASD injury cases previously litigated in the Program, in which well-meaning parents pursue questionable medical treatments that may themselves have unpredictable complications, while also insisting that vaccination played some role in the child's condition. *See, e.g.*, *Anderson*, 2016 WL 8256278, at *5 n.7. The causation theory in this case has numerous "echoes" with such previously-litigated claims—in particular to the extent it sought to establish that certain aspects of A.Y.'s ASD-related behaviors were worsened by the purported varicella reactivation—and those parallels underscored for me why resolution on the papers was preferable to hearing.

history do not permit me to conclude that he either did experience a varicella infection attributable to vaccination, or that such an infection worsened existing health problems from which he suffered. And I do not find that any of A.Y.'s ASD-associated behavioral problems could possibly have been worsened by a purported varicella infection due to viral reactivation.

Accordingly, this claim is dismissed. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.[35] Petitioners are also directed to file a status report on or before August 28, 2020 indicating what action they wish to take with respect to the remaining two claims in this case, in light of my Decision.

IT IS SO ORDERED.

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

[35] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.