In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1571V

(not to be published)

* *	Special Master Corcoran
MICHAEL BRAUN, *on behalf of son* H.B., *a minor*, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Filed: January 25, 2019
	Dismissal of Petition; Vaccine Act; Denial Without Hearing; FluMist Vaccine; Encephalopathy; Developmental Delay.

Joseph P. Shannon, Shannon Law Group, P.C., Woodbridge, IL, for Petitioner.

Daniel A. Principato, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DISMISSING PETITION[1]

On October 20, 2017, Michael Braun filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program") on behalf of his minor son, H.B.[2] In it, Petitioner alleged that H.B. developed an encephalopathy and resulting developmental delays following his receipt of the FluMist influenza ("flu") vaccine on October 22, 2014. *See generally* Petition (ECF No. 1) ("Pet.").

[1] Although I am not formally designating this Decision for publication, it will nevertheless be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means 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 Decision in its present form will be available. *Id.*

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

Summation of Relevant Facts

H.B. was born on May 16, 2006. Ex. 1 at 5. It appears from the filed records that H.B. was relatively healthy and developing normally during his first year of life. The records reveal treatment for various illnesses (including ITP, a skin rash, and Lyme disease). *See id.* at 114, 126, 236-39, 254, 271.

During H.B.'s eighteen-month check-up on November 16, 2007, his treating pediatrician assessed him with a speech delay and 2-3 word jargon. Ex. 1 at 131. His two-year well-visit exam notes included a similar finding. *Id.* at 138 (H.B.'s speech was on a 15-18 month level). Speech delays were noted again during both his three-year and four-year well-child appointments. *Id.* at 139-41. His four-year visit also noted sensory issues. *Id.* at 141.

At a five-year well-child visit on May 20, 2011, H.B.'s pediatrician assessed him with a "listening comprehension disability" in addition to speech concerns. Ex. 1 at 274. Records also indicated that H.B. started occupational therapy in February 2011 for decreased visual motor integration, visual perception, and motor coordination. *Id.* at 1522-23. Preschool assessment records included in the pediatrician's file indicated that H.B.'s language and writing skills were in the low range. *Id.* at 1468-69. H.B.'s six, seven, and eight-year well-visits continued to note that H.B. was attending occupational and speech therapy for the above-noted concerns. *Id.* at 280, 287-88, 291-92.

H.B. was eight-years-old when he received the FluMist vaccine on October 22, 2014. Ex. 1 at 2. No adverse symptoms were noted at the time of vaccine administration. H.B.'s next medical visit following his receipt of the FluMist vaccine nearly two months later, occurred on December 15, 2014. H.B. presented to a neurologist for "evaluation of his inattention" and learning disabilities. Ex. 1 at 219. He was assessed with ADHD, inattentive type. *Id.* at 220. The records from this December 2014 visit make no mention of any concerns or symptoms from the time of the vaccine at issue. *See id.* at 219-20. Thereafter, on January 28, 2015, H.B. presented to his pediatrician with complaints of speech, recall, and slight motor regression, though treatment notes indicated "no obvious signs of increasing . . . regression." *Id.* at 302-03. H.B. was assessed with "[l]earning difficulties" and possible underlying developmental delay. *Id.* at 303.[3]

Neurodevelopmental evaluations conducted on February 18, 2015, and February 21, 2015, noted a history of "[r]egression in skills" with onset in November-December 2014, though the exam also noted H.B.'s caretakers reported that he had experienced processing issues and academic struggles from an early age. Ex. 1 at 170-71. His receipt of the FluMist vaccine was

[3] School assessment records from close-in-time to vaccination administration note that H.B.'s parents were concerned that he was regressing further in both speech/language and the ability to follow directions. *See* Ex. 1 at 1599-1600 (evaluation from November 24, 2015), 1605 (February 5, 2015 letter from speech therapist noting an increase in regression and focusing issues since the school year started).

included in the health history, but it was noted that H.B. exhibited no signs of a reaction. *Id.* at 173. The examination revealed below average processing/memory skills and "severe" fine motor/visual motor deficits, along with below average gross motor and language skills. *Id.* at 177-79. The impression included progressive neurodegenerative disorder, neuro-metabolic disorder, mitochondrial disorder/abnormalities, and storage disorder. *Id.* at 179. An MRI conducted on March 3, 2015, revealed normal imaging. *Id.* at 22.

H.B. was seen by a neurologist at Goryeb Children's Hospital ("Goryeb Children's") on March 17, 2015. Ex. 1 at 305. His past health history was significant for "developmental delays most motor" with onset in the "first year of life" (well before the vaccination at issue). *Id.* at 307. His neurological exam revealed an abnormal mental status, along with motor dysfunction. *Id.* The assessment included a movement disorder and developmental delay. *Id.* at 305. Shortly thereafter, H.B. presented for a rheumatology consult at Goryeb Children's. *Id.* at 185-89. The health history taken during this visit (similar to those taken earlier) noted an onset of language/speech regression and behavioral changes over the course of the year. *Id.* at 189. H.B.'s receipt of the FluMist vaccine was mentioned during the visit, but notes asserted (contrary to the medical history) the vaccination "preceded many of his symptoms according to his mother." *Id.* at 186.

An April 1, 2015, pediatric visit note indicated that H.B. was "being evaluated for worsening ADHD symptoms." Ex. 1 at 262. H.B.'s father reported during this visit that H.B.'s symptoms "began soon after" receipt of the FluMist vaccine in October 2014. *Id.* H.B. was seen by an infectious disease specialist at Goryeb Children's the following day, on April 2, 2015. *Id.* at 476. H.B.'s health history included an onset of deterioration in handwriting and concentration at the beginning of the 2014 school year. *Id.* Notes indicate that the specialist considered diagnoses of Sydenham's chorea and PANDAS, but did not arrive at a firm conclusion. *Id.* Subsequent evaluations during June 2015 show further discussion of a movement disorder diagnosis, as well as post-acute immune syndrome, and active Lyme disease. *Id.* at 168. The record also reveals that H.B. was hospitalized for psychosis (including episodes of crying, uncontrolled screaming, and hallucinating) during the first week of June 2015. *Id.* at 565-70. Notably, this hospital record also referenced a concern for autism. *Id.* at 566. An MRI conducted during the hospitalization revealed normal imaging. *Id.* at 1000-01.

H.B. was seen by another neurologist, Dr. Rosario Triffiletti, in April 2015 for further evaluation of his overall health course. Ex. 1 at 1151, 1153, 1159-60. Exam notes from an April 22, 2015 visit included a reference to an undated "flu vaccine[,]" but offered no opinion regarding its relationship to H.B.'s symptoms. *See id.* at 1160. The April 22nd note also included a concern for separation anxiety and speech delay. *Id.* Notes from a November 20th visit mentioned a "dx autoimmune encephalopathy[,]" but similarly included no description or opinion regarding onset or trigger. *Id.* at 1153. Follow-up visits with Dr. Triffiletti also indicated concerns for additional diagnoses including anxiety, OCD behaviors, and autism. *Id.* at 1152

(December 20, 2016 note indicating concern for anxiety and OCD behaviors), 1150 (May 30, 2017 note indicating "ASD progressing"). The records from visits with Dr. Triffiletti indicate H.B. was treated with IVIG for a number of months. *See, e.g.*, Ex. 1127, 1150, 1152, 1174.

The final record of note is dated October 17, 2016, and references an additional neurology consult from Children's Hospital of Pennsylvania ("CHOP"). Ex. 1 at 379-84. H.B.'s health history included regression (with onset in 2014), PANDAS, ADHD, Lyme disease, and Sydenham's chorea. *Id.* at 379-80. It was also noted that he was receiving IVIG treatment from Dr. Triffiletti for possible PANDAS. *Id.* at 380. The differential diagnoses included autoimmune encephalitis and genetic/metabolic disorder. *Id.* at 384. Lab testing conducted during a follow-up visit at CHOP, however, revealed negative serum NMDA and Mayo autoimmune encephalitis panels. *Id.* at 830-31. An additional brain MRI conducted in November 2016 was unremarkable. *Id.* at 830.

Procedural History

Petitioner originally filed this petition *pro se*, but upon motion to substitute counsel, Joseph Shannon became the attorney of record on January 23, 2018 (ECF No. 11). Counsel filed the majority of H.B.'s medical records in May 2018. *See* ECF Nos. 16-21. Thereafter, Respondent filed the Rule 4(c) Report on July 31, 2018, contesting Petitioner's right to an entitlement award. *See* Respondent's Report, filed July 31, 2018 (ECF No. 25). Specifically, Respondent asserted that the filed medical records did not support Petitioner's contention that H.B. suffered from an acute encephalopathy close-in-time to receipt of the FluMist vaccination. The report similarly revealed that H.B. had experienced developmental problems in the years prior to vaccination (as early as 2008).

Following the filing of records and the Rule 4(c) Report, I held a status conference with the parties on August 23, 2018, at which time I outlined my concerns to Petitioner about his claim's viability. *See* Order, dated Aug. 23, 2018 (ECF No. 26) ("August 23rd Order"). Given the existence of numerous other decisions pursuing theories similar to the one proposed herein (involving a claimed injury of a developmental problems after an encephalopathic event), I impressed upon Petitioner my strongly-held view that his claim likely faced reasonable basis problems given its overall nature. *Id.* at 1-2. In particular, the record did not support his assertion that H.B. had experienced any type of encephalopathic reaction to the FluMist vaccine he received, or that his developmental regression was more than temporally related to any symptom alleged to be vaccine-induced. Moreover, I noted that H.B.'s treaters expressed concern for developmental regression in the years *prior* to his receipt of the FluMist vaccine. Thus, based on record evidence, it did not appear likely that Petitioner could demonstrate that the FluMist vaccine initiated (or worsened) any of the adverse symptoms H.B. experienced thereafter.

In light of the above, I set a deadline for Petitioner to show cause why his claim should not be dismissed. *See* August 23rd Order at 2. I urged counsel to cite to H.B.'s filed medical

records (including any evidence of acute encephalopathic reaction close-in-time to vaccination), and to differentiate this claim from others that have been unsuccessfully litigated the in Program. *Id.*

Parties' Respective Arguments

Petitioner filed a brief responding to my Show Cause Order on October 10, 2018. *See* Brief in Support of Reasonable Basis, filed Oct. 10, 2018 (ECF No. 27-1) ("Brief"). In it, Petitioner argues that H.B.'s school record evidences a "severe regression in H.B.'s speech and gross motor skills, and neurologic function" within approximately two weeks of his receipt of the FluMist vaccine. *Id.* at 1 (citing Ex. 1 at 1568; Affidavit of Michael Braun, dated May 1, 2018, filed as Ex. 1 at 1443-45 (ECF No. 21)). For additional support, Petitioner cites to medical record evidence (importantly, dated over *one year* post-vaccination) indicating H.B.'s treating neurologist, Dr. Triffiletti, diagnosed him with an encephalopathic reaction "with sudden onset following an influenza vaccine," and resulting in various developmental problems. *Id.* (citing Ex. 1 at 916; Ex. 3 at 1).

Petitioner next offered case law in support of his argument that his claim has reasonable basis to proceed. Brief at 9-12 (citing *Spahn v. Sec'y of Health & Human Servs.*, No. 09-386V, 2014 WL 12721080 (Fed. Cl. Spec. Mstr. Sept. 11, 2014), *mot. for review den'd*, 133 Fed. Cl. 588 (2017)). In *Spahn*, the presiding special master allowed a facial tics/Td vaccine claim to proceed to the expert stage (due primarily to opposing counsel's argument that petitioner could not satisfy the *Althen* one prong). Nevertheless, Petitioner argues the record evidence in the present matter is factually similar to the evidence offered in *Spahn*, and he thus asks that I allow him to file an expert report in support of his claim.[4]

Petitioner also submitted additional medical records in support of his claim. *See* ECF No. 27-2 (undated letter from school speech pathologist indicating that H.B. appeared to regress in language skill around December 2014); ECF No. 27-3 (August 3, 2018 letter from Dr. Triffiletti noting that H.B. has been treated for autoimmune encephalopathy following receipt of the FluMist vaccine). Two medical articles discussing encephalopathy following influenza A/B infection (but not vaccination) also accompanied Petitioner's show cause brief. *See generally* Ex. 4 & 5. In addition, Petitioner cites to various cases in the Program awarding entitlement for a FluMist-induced vaccine injury. *Id.* at 12-13 (citing *L.A. v. Sec'y of Health & Human Servs.*, No. 12-629V, 2016 WL 7664473 (Fed. Cl. Spec. Mstr. Dec. 15, 2016) (awarding entitlement for FluMist/encephalitis injury with two-day onset); *Agnew v. Sec'y of Health & Human Servs.*, No. 12-551V, 2016 WL 1612853 (Fed. Cl. Spec. Mstr. Mar. 30, 2016) (awarding entitlement for FluMist/acute hepatitis injury with ten-day onset); *Day v. Sec'y of Health & Human Servs.*,

[4] Petitioner's brief further indicates that counsel spoke with Dr. Lawrence Steinman (prior to filing the claim). According to counsel, Dr. Steinman reviewed the case file and informed counsel that the facts of the present matter could plausibly support a Program claim. Brief at 12-13.

No. 12-551, 2015 WL 8028393 (Fed. Cl. Spec. Mstr. Nov. 13, 2015) (awarding entitlement for HPV/FluMist/neuromyelitis optica injury with three-day onset)).[5]

Respondent filed a response on November 9, 2018. *See* Response, dated Nov. 9, 2018 (ECF No. 29). Respondent maintains that Petitioner has offered no contemporaneous medical record evidence credibly establishing that H.B. suffered an encephalopathy following his October 2014 vaccination. *Id.* at 3-4. In particular, Respondent argues that the treater statements offered by Dr. Trifilletti to be unpersuasive given the year-long gap between his medical evaluation and Petitioner's alleged injury. *Id.* Accordingly, Respondent asserts that the documented medical record evidences nothing more than a weak temporal relationship between receipt of the FluMist vaccine and onset of developmental regression thereafter, assuming that onset of H.B.'s developmental problems did not in fact actually begin well before he received the vaccine at issue. *Id.* at 4.

ANALYSIS

To receive compensation under the Vaccine Program, a petitioner must prove either (1) that he suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of his vaccinations, or (2) that he suffered an injury that was actually caused by a vaccine. *See* §§ 13(a)(1)(A) and 11(c)(1). An examination of the record, however, does not uncover any evidence that H.B. suffered a "Table Injury." Accordingly, Petitioner seeks to establish entitlement via a causation-in-fact, non-Table claim – meaning he must meet the test for such a claim set forth by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005).

Petitioner has had several chances to offer evidence into the record that would support his claim. The record, however, does not contain sufficient persuasive evidence establishing that H.B.'s developmental problems were initiated by the FluMist vaccine via the theory proffered herein. (*see* § 11(c)(1)(C)(i)-(ii)). Thus, after careful review of the medical records and Petitioner's filings, I conclude that Petitioner will not be able to establish preponderant evidence in favor of his claim, and therefore the matter should not proceed any further.

My decision is rooted in both the facts of this case as well as applicable decisions in previously-litigated matters involving causation theories highly similar to the present. *See, e.g.*, *Austin v. Sec'y of Health & Human Servs.*, No. 5-579V, 2018 WL 32386608 (Fed. Cl. Spec. Mstr. May 15, 2018), *aff'd*, slip op (Fed. Cl. Oct. 23, 2018); *R.V. v. Sec'y of Health & Human Servs.*, No. 08-504V, 2016 WL 3882519 (Fed. Cl. Spec. Mstr. Feb. 19, 2016), *mot. for review den'd*, 127 Fed. Cl. 136 (2016). The theory that vaccines can cause developmental injuries (in the absence of strong proof of encephalopathy) have rarely been successful in the Program, and I find no compelling reason here to diverge from those holdings. Petitioner has not offered

[5] Counsel also filed five videos taken of H.B. by his father. *See* ECF No. 28.

evidence showing how H.B.'s case is factually different from those already decided.

In particular, there is a lack of medical record evidence close-in-time to H.B.'s receipt of the FluMist vaccine supporting Petitioner's contention that H.B. experienced an acute encephalopathic reaction. Counsel maintains that H.B.'s regression was first seen by school officials, as evidenced by an educational assessment dated November 25, 2014 (over one month following H.B.'s receipt of the FluMist vaccine), and a speech evaluation (dated over two months post-vaccination). Brief at 3; Ex. 1 at 1586 (IEP note indicating H.B. was struggling to process information); Ex. 2 at 1 (speech note indicating regression in oral motor function). Notably, however, medical visits close-in-time to H.B.'s receipt of the FluMist vaccine make no mention of any encephalopathic reaction. *See, e.g.*, Ex. 1 at 219-20 (December 15, 2014 assessment of ADHD, inattentive type), 302-03 (January 28, 2015 assessment for speech and fine motor regression following diagnosis of ADHD).

Admittedly, the record does evidence some treater concern for regression following receipt of the FluMist vaccine, but such records evidence nothing more than a temporal relationship between vaccination and injury (given the lack of record support for an acute encephalopathic reaction). *See, e.g.*, Ex. 1 at 168, 170-73, 177-79, 271, 262, 305, 565-66; *see also Austin*, 2018 WL 3238608, at *23-24 (discussing the medical record evidence necessary to establish a non-Table encephalopathy claim). Moreover, such records must be weighed against the substantial medical evidence strongly suggesting that H.B. had experienced developmental problems long before the vaccination. *See, e.g.*, Ex. 1 at 139-41, 141, 274, 281, 288, 307.

The record next reveals that H.B. was hospitalized in late May 2015 for various adverse symptoms (including screaming episodes, visual/auditory hallucinations, and generalized distress). *See* Ex. 1 at 966 (May 20, 2015 hospitalization record). Notably, H.B.'s hospital record revealed a concern for psychosis and autism. *Id.* at 565-66. A closer examination of the record, however, reveals that no hospital treater opined that H.B. had experienced an encephalopathic reaction induced by a vaccine. In addition, evidence that could corroborate that an encephalopathy did in fact occur at this time, such as an MRI, revealed no abnormalities that might corroborate this assertion. *See* Ex. 1 at 1000-01.

As noted above, H.B. was first diagnosed with an encephalopathy by Dr. Triffiletti in November 2015 (over one year after his receipt of the Flumist vaccine). Ex. 1 at 1150-53. Admittedly, records from a November 4, 2015 visit indicate that H.B. was assessed with an encephalopathic reaction. *Id.* at 1153. The November 4th record, however, makes no mention of H.B.'s receipt of FluMist, but seems to be based on the symptoms reported from H.B.'s May 2015 hospitalization—over six months from the date of vaccination. *See id.* A later-in-time letter, dated August 3, 2018, and authored by Dr. Triffiletti, clarified that he assessed H.B. with an autoimmune encephalopathy following receipt of the FluMist vaccine in 2014 (Ex. 3 at 1). Based on my overall assessment, however, Dr. Triffilett's opinion regarding causation seems to

be based primarily on the health history provided by H.B.'s caretakers (as it is clear from the record that the he did not examine H.B. until over one-year post-vaccination). In addition, the disparity between Dr. Triffiletti's notes from 2015 and his more recent 2018 letter further call into question the reliability of any association of H.B.'s symptoms to the Flumist vaccine. Such evidence cannot establish a causal link between an injury and a vaccination.

The remaining records make no mention of any purported vaccine-induced injury (nor do they attempt to link H.B.'s alleged encephalopathic reaction to any symptoms he experienced). Notably, as emphasized above, multiple filed records also reflect that H.B.'s treaters expressed concern for developmental problems *prior* to his receipt of the FluMist vaccine in 2014. *See, e.g.*, Ex. 1 at 131, 138-39; *see also* Ex. 1 at 271-74, 1522-23, 1467-69. Although Petitioner directly disputes any assertion that these earlier-in-time records are related to the onset of H.B.'s injuries alleged herein, Petitioner did not offer persuasive medical or scientific support analyzing these records and distinguishing H.B.'s symptoms from those alleged to be vaccine-caused.

Furthermore, the case law cited by Petitioner in attempts to bolster the claim is not supportive of a finding of reasonable basis to proceed. Petitioner cites to *Spahn* (involving a claimed injury of tics induced by the Td vaccine), but in that case the special master ordered expert reports based on a dispute regarding the ability of the Td vaccine to cause tics (as it relates to the *Althen* one prong). *See Spahn*, 2014 WL 12721080, at *4. And as I have discussed extensively above, *this* case's deficiencies center on the lack of persuasive medical record evidence supporting Petitioner's contention that H.B. experienced a vaccine-induced encephalopathic reaction. *Spahn* is thus unhelpful to Petitioner as it does not explain why I should allow him to proceed with this case in light of such a deficiency. The remaining cases (*L.A.*, *Agnew*, and *Day*) involve injuries that are distinguishable from those alleged herein (or involve an onset significantly closer-in-time to the alleged injury). More importantly, these cases involved at least <u>some</u> persuasive medical record evidence supporting the various theories alleged therein (unlike the present matter).

Ultimately, the medical record itself is fatal to Petitioner's claim. The record contains unexplained and unrebutted facts that suggest either H.B.'s injuries predated vaccination, or that they are attributable to an entirely different illness (given the multiple differential explanations noted in his overall health course). But most importantly, the record contains no evidence of an encephalopathic injury *close-in-time* to H.B.'s receipt of the FluMist vaccine, and the treater statements offered over *one year* post-vaccination are not persuasive given the extensive contemporaneous record. An expert opinion would not aid Petitioner in light of this absence. The plain record itself, without such further supplementation or substantiation, does not support Petitioner's claim, and therefore I cannot rule in his favor based upon the record as it stands.

Given the above, the claim as alleged lacks reasonable basis, and is appropriately dismissed. In so doing, I am aware of Petitioner's disappointment, and his fervent desire

(motivated by a reasonable wish to provide good care for H.B.) to proceed with the claim. But I must balance such concerns against the waste of judicial resources that will be occasioned by allowing this matter to go forward. My experience with similar claims tells me (based on review of the record) that this claim will not succeed where countless others failed. Because Petitioner has not – despite due opportunity – shown otherwise, I must **DISMISS** his claim.

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 accordance with this decision.[6]

IT IS SO ORDERED.

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

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