

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

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JACQUELINE M. DUNCAN,)	
)	
Petitioner,)	
)	
v.)	No. 16-1367V
)	
SECRETARY OF HEALTH AND)	Originally Filed: April 19, 2021
HUMAN SERVICES,)	Re-issued: May 4, 2021
)	
Respondent.)	
_____)	

OPINION AND ORDER¹

Petitioner Jacqueline M. Duncan seeks review of a decision denying her request for vaccine injury compensation. Ms. Duncan filed her petition in October 2016 pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et seq.* (the “Vaccine Act”), alleging that a human papillomavirus (“HPV”) vaccine she received on October 28, 2013 significantly aggravated her Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infections (“PANDAS”). In October 2020, the Special Master dismissed her petition for insufficient proof. He determined that after four years of attempting to develop her case Ms. Duncan had failed to present “minimally competent evidence to substantiate her claim.” Decision Den. Comp. at 1, ECF No. 107. Ms. Duncan timely filed a Motion for Review before this Court, raising primarily procedural objections to the Special Master’s decision.

For the reasons that follow, the Court **DENIES** her motion.

¹ The Court originally issued this opinion under seal on April 19, 2021 and allowed the parties 14 days from the date of filing to object to the public disclosure of any information furnished by that party. Neither party proposed any redactions, and thus the opinion is publicly released in full.

I. BACKGROUND

A. Factual History

1. Ms. Duncan's Pre-Vaccination Condition

Ms. Duncan was born on February 5, 1997. Petr.'s Pet. ¶ 2, ECF No. 1. Prior to receiving the HPV vaccine, she had a number of significant events in her medical history. Ms. Duncan averred that in her early teens she began to struggle with “serious and repeated bouts [of] strep and tonsil problems.” *Id.* ¶ 5. Due to this history, her doctor recommended a tonsillectomy, which she underwent in November 2011. Petr.'s Ex. 25 (Rochester General Hospital Records) at 30–31,² ECF No. 9-21. Ms. Duncan was then in the ninth grade. ECF No. 1 ¶ 5. Unfortunately, her post-operative recovery was complicated. She missed at least a month of school and developed “severe headaches, fatigue, [and] weakness” following her surgery. *Id.*; *see* Petr.'s Ex. 23 (Records of Dr. Alice Tariot) at 11, ECF No. 9-19; *see also* Petr.'s Ex. 5 (Step By Step Academy Records) at 35, ECF No. 9-1 (noting a “3 month healing process”).

Ms. Duncan's medical records document that her complaints of aches and pains pre-dated her tonsillectomy, beginning in the eighth grade. ECF No. 9-19 at 55. Around the same time, she began to refuse to attend school due to anxiety and depression. ECF No. 9-1 at 35. Per a report from her psychiatrist, these symptoms worsened following her November 2011 surgery. ECF No. 9-19 at 70. After episodes of self-injurious behavior, she was admitted in April 2012 to an intensive, multiweek outpatient psychiatric program and discharged with diagnoses of generalized anxiety disorder, bipolar disorder, and complaints of aches and pains. *Id.*; *see* ECF No. 9-1 at 35.

With additional outside counseling, Ms. Duncan eventually was able to return to school and joined the cheerleading squad during her sophomore year. ECF No. 9-1 at 35; *see* ECF No. 1

² Citations to Petitioner's exhibits refer to the ECF page number of the relevant document.

¶ 7. In October 2012, however, she suffered a concussion during cheerleading practice. Petr.'s Ex. 27 (Records of Dr. Sharada Menon) at 25, ECF No. 24-1; *see* ECF No. 1 ¶ 7. Ms. Duncan claims that her head injury worsened her condition. ECF No. 1 ¶ 7; *see* ECF No. 24-1 at 22 (reporting headache, throbbing pain, nausea, and sensitivity to light two months after concussion). In the months prior to receiving the HPV vaccine, Ms. Duncan's records show that she was taken to an urgent care for chest pain and reported feeling sick and tired. ECF No. 24-1 at 17.

2. Ms. Duncan's Post-Vaccination Condition

On October 28, 2013, Ms. Duncan received the HPV vaccine.³ Both Ms. Duncan and her mother claimed that Ms. Duncan experienced severe symptoms "within a few days" of the injection. Aff. of Jacqueline M. Duncan ¶ 17, ECF No. 1-2; *see* Aff. of Khrystine Duncan ¶ 16, ECF No. 1-3. These symptoms included "horrible fatigue, joint pain, headaches," "electric shocks" through her body, cold and grayish-blue skin, and the feeling of "bee stings." ECF No. 1-2 ¶ 17. Ms. Duncan alleged that her fatigue and physical difficulties became "five times worse than they were before the [HPV vaccine]." *Id.* ¶ 20.

Ms. Duncan did not identify any medical records created at or immediately after the time of her vaccination that document these extreme symptoms. Based on the Court's review, Ms. Duncan was seen by her primary care physician on November 13, 2013 for complaints of stomach pain, sore throat, and fatigue for three days. ECF No. 24-1 at 12. Her doctor diagnosed her with an unspecified viral infection. *Id.* Ms. Duncan also was seen on January 2, 2014 for sore throat, headache, body ache, and left ear pain for two weeks. *Id.* at 11. She was assessed as having acute

³ This was Ms. Duncan's second dose of the HPV vaccine, the first having been administered in 2011 with no negative side effects. ECF No. 1 ¶ 8. She does not allege that her first dose contributed to a worsening of her condition. Unless otherwise specified, all references to the HPV vaccine in this opinion refer to the vaccine she received in October 2013.

sinusitis. *Id.* However, on January 14, 2014, Ms. Duncan presented at Rochester General Hospital's emergency room with complaints of "bee stings all over [her] body," fatigue, weakness, nausea, dizziness, chest pain, and anxiety. Petr.'s Ex. 24 (Rochester General Hospital Records) at 10, ECF No. 9-20; *see* ECF No. 24-1 at 10. She described a "sudden onset" of shooting nerve pain that evening. ECF No. 9-20 at 10. She also reported having a virus, sinus infection, and ear ache the week prior and sleep problems "for [the] past couple days." *Id.* Ms. Duncan was discharged with diagnoses of nerve pain and dizziness. *Id.* at 14.

Following her emergency room visit, Ms. Duncan's medical records document numerous visits to a variety of practitioners. In January 2014, Ms. Duncan saw a rheumatologist at the University of Rochester Medical Center. Petr.'s Ex. 8 (Records of Dr. Homaira Rahimi) at 2, ECF No. 9-4. According to the medical history from the appointment, Ms. Duncan was "well until about 2–3 years ago, when she began to develop fatigue and body pains." *Id.* Ms. Duncan also reported that "[a]bout 2 weeks ago" she "developed bee sting sensations on her body." *Id.* at 3. Dr. Rahimi diagnosed Ms. Duncan with reflex neurovascular dystrophy ("RND"), which was described as analogous to fibromyalgia in adults. *Id.* at 2. Dr. Rahimi did not believe there was evidence of an autoimmune condition. *Id.* at 6. In addition to counseling, Dr. Rahimi recommended physical therapy for treatment of Ms. Duncan's RND, *id.*, which Ms. Duncan participated in from February to April 2014, Petr.'s Ex. 26B (Strong Memorial Hospital Records) at 6–7, ECF No. 9-23.

In February 2014, Ms. Duncan was evaluated by a specialist, Dr. Susan Schulman, and diagnosed with PANDAS. ECF No. 24-1 at 125–128. Dr. Schulman believed that Ms. Duncan has been suffering from undiagnosed PANDAS since 2010 (her eighth-grade year), which worsened after her 2011 tonsillectomy. *Id.* at 125. Dr. Schulman began a protocol of antibiotics

and vitamins and recommended intravenous immunoglobulin therapy. *Id.* at 129; *see* Petr.'s Ex. 7 (Records of Dr. Susan Schulman) at 2, ECF No. 9-3.

In 2014, Ms. Duncan moved with her family to Ohio before starting her senior year of high school. ECF No. 1-3 ¶ 22. Ms. Duncan began seeing a new primary care physician, Dr. Lindsay Wylie. ECF No. 1-2 ¶ 21. At her initial appointment with Dr. Wylie, Ms. Duncan discussed her PANDAS diagnosis. Petr.'s Ex. 12 (Records of Dr. Lindsay Wylie) at 20, ECF No. 9-8. According to Ms. Duncan, Dr. Wylie stated that Ms. Duncan's prior strep and tonsillectomy problems could have been aggravated by her HPV vaccine. ECF No. 1-2 ¶ 21. Dr. Wylie's records document several subsequent visits for Ms. Duncan's complaints of, *inter alia*, sore throat, headache, ear pain, abdominal pain, and night sweats. ECF No. 9-8 at 3, 5, 7, 10, 16.

Ms. Duncan also began seeing Dr. Allen Lewis in 2014. Based on lab work conducted in February 2015, Dr. Lewis recommended treating Ms. Duncan for elevated levels of, *inter alia*, Lyme and strep A. Petr.'s Ex. 9 (Records of Dr. Allen Lewis) at 14, ECF No. 9-5; *see* Petr.'s Ex. 10 (Integrative Pediatrics of Ohio Lab Results), ECF No. 9-6. Dr. Lewis noted that Ms. Duncan's symptoms worsened after she underwent an explorative laparoscopy in September 2015, ECF No. 9-5 at 5, including "a lot of neuropathy" and "bee sting type of sensations," *id.* at 3. In addition to other treatments, Dr. Lewis recommended a consult with Dr. Michael Joseph for Ms. Duncan's pain. *Id.* at 5. Ms. Duncan's mother claimed that Dr. Lewis "felt that . . . both [Ms. Duncan's] PANDAS and Lyme were exacerbated or caused" by the HPV vaccine. ECF No. 1-3 ¶ 23.

Ms. Duncan had her initial visit with Dr. Joseph in March 2016. Petr.'s Ex. 28 (Records of Dr. Michael Joseph) at 11, ECF No. 26. He noted Ms. Duncan's history of tonsillectomy followed by symptoms of anxiety, fatigue, physical sensitivity, and night terrors. *Id.* These symptoms returned following Ms. Duncan's concussion, and she reported "increased muscle

spasms, fatigue, needle[] like pain, [and] drenching sweat.” *Id.* Dr. Joseph’s records document her prior diagnoses of RND, PANDAS, and Lyme, as well as symptoms of “[r]ock hard muscles, freezing feeling,” “[s]hock pain,” and “[f]atigue every day.” *Id.* Per a September 2016 medical record, Ms. Duncan and her mother reported that they “had a revelation that her symptoms became significantly worse after her [HPV] vaccine.” *Id.* at 55.

Aside from her physical condition, Ms. Duncan claimed her academic performance and social activities declined after receiving the HPV vaccine in October 2013. ECF No. 1-2 ¶¶ 4, 9, 14; *see* ECF No. 1-3 ¶¶ 4, 9, 21, 22. Ms. Duncan’s mother alleged that following her 2011 tonsillectomy Ms. Duncan was unable to return to school for three months and required tutoring. ECF No. 1-3 ¶ 9. Ms. Duncan’s school records show that in her freshman year (2011), before she received the HPV vaccine, Ms. Duncan received only two credits because she did not pass most of her courses. Petr.’s Ex. 29 (Wayne Central School District Records) at 1, ECF No. 28-1. Ms. Duncan also was unable to return to dancing, an activity she previously participated in competitively. ECF No. 1-3 ¶¶ 4, 9. Although Ms. Duncan alleged that she was able to return to school during her sophomore year and participate in cheerleading, following her HPV vaccination, she spent her junior year either at home with a tutor or in an alternative classroom for students with special needs. ECF No. 1-2 ¶¶ 12, 14; *see* ECF No. 1-3 ¶¶ 12, 21. Ms. Duncan’s school records show she received 4.5 credits during her junior year and had an unweighted GPA of 76. ECF No. 28-1 at 1. Ms. Duncan took classes online during her senior year, receiving the highest academic scores of her high school years and graduating in May 2015. ECF No. 1-3 ¶ 22; *see* Petr.’s Ex. 30 (Olentangy Local School District Records) at 71, ECF No. 28-2.

B. Proceedings Before the Special Master

On October 19, 2016, Ms. Duncan filed a petition seeking vaccine injury compensation. The petition alleged that the HPV vaccine Ms. Duncan received in October 2013 significantly aggravated her underlying PANDAS. ECF No. 1 ¶ 10. Ms. Duncan subsequently filed medical records and later a statement of completion on December 27, 2016.⁴ Petr.'s Am. Statement of Completion, ECF No. 17.

Based on the evidence submitted by Ms. Duncan, Respondent filed a Rule 4(c) report in March 2017, concluding that she was not entitled to compensation. Respt.'s Rule 4(c) Report at 1–2, ECF No. 20. Respondent asserted, *inter alia*, that Ms. Duncan failed to provide a reliable medical theory connecting the HPV vaccine to any medical conditions she allegedly suffered after the vaccination. *Id.* at 8. Moreover, Respondent noted that, despite Ms. Duncan's allegation that she suffered severe symptoms within days, none of the contemporaneous medical records indicated that Ms. Duncan became much worse in the weeks and months after her vaccination. *Id.* at 8–9.

In April 2017, Ms. Duncan filed a one-page letter from Dr. Joseph, stating his opinion that the HPV vaccine “greatly exacerbated” Ms. Duncan's symptoms. Petr.'s Ex. 31 (Letter of Dr. Joseph) at 1, ECF No. 30-1. The Special Master determined, however, that Dr. Joseph's letter did not, by itself, establish that the HPV vaccine aggravated Ms. Duncan's PANDAS. *See* ECF No. 107 at 2. To assist Ms. Duncan and her attorney, the Special Master proposed a set of instructions to guide experts in the presentation of vaccine-related opinions, including specific topics that should be discussed in each party's expert reports. *See* Order (July 21, 2017), ECF No. 48; *see also* Order Regarding Expert Reports (Aug. 8, 2017), ECF No. 49. In a series of status reports

⁴ Since filing her initial Statement of Completion, Ms. Duncan has on numerous occasions supplemented her Exhibit List with a variety of additional materials and filed an additional Amended Statement of Completion on May 12, 2017 (ECF No. 35).

filed between September 2017 and August 2018, Ms. Duncan's counsel reported difficulties obtaining additional expert reports.⁵

Having not filed any additional or supplemental expert reports for over a year, the Special Master held a status conference in September 2018. Order (Sept. 28, 2018) at 1, ECF No. 77. Ms. Duncan's counsel stated during the conference that he was attempting to obtain an opinion from a biomedical engineer, as well as a treating physician. *Id.* The Special Master explained that opinions from individuals without medical degrees are uncommon in the Vaccine Program and generally less persuasive. *Id.* The Special Master set a deadline for Ms. Duncan to submit any expert reports, and he warned that further delay could result in a show cause order. *Id.*

In November 2018, Ms. Duncan submitted a report from Dr. James Lyons-Weiler. Petr.'s Ex. 39 (Expert Report of Dr. Lyons-Weiler), ECF No. 78. Dr. Lyons-Weiler opined that the "HPV vaccination can significantly aggravate PANDAS through molecular mimicry." *Id.* at 4. He explained that the adjuvant in the vaccine can "caus[e] the immune system to mount an attack against foreign proteins that are co-present at the time of immunization, e.g., chronic or repeated Strep-A infection." *Id.* at 4–5. Dr. Lyons-Weiler opined to a "reasonable degree of scientific probability" that the HPV vaccine caused a significant aggravation of Ms. Duncan's PANDAS. *Id.* at 1. At a subsequent status conference, the Special Master noted several substantive deficiencies with Dr. Lyons-Weiler's report and ordered supplemental information. Order (Feb.

⁵ For example, Ms. Duncan filed status reports on September 22, 2017 (ECF No. 53) (advising that Dr. Joseph and Dr. Wiley were not responsive to counsel's request for expert reports); November 7, 2017 (ECF No. 55) (advising that counsel was attempting to retain an expert in immunology); December 5, 2017 (ECF No. 61) (reporting that the immunologist retained by counsel would not be able to provide a report in compliance with the instructions); April 9, 2018 (ECF No. 68) (documenting unsuccessful efforts to retain other experts); May 11, 2018 (ECF No. 70) (same); June 11, 2018 (ECF No. 72) (same); July 11, 2018 (ECF No. 74) (same); and August 27, 2018 (ECF No. 76) (same).

22, 2019) at 1, ECF No. 79. The Special Master also set a deadline for an expert report of a treating physician or other medical doctor. *Id.*

After requesting several enlargements of time, all of which were granted, Ms. Duncan filed a supplemental report by Dr. Joseph in November 2019. Petr.'s Ex. 58 (Expert Report of Dr. Michael Joseph), ECF No. 96-1. Like Dr. Lyons-Weiler, Dr. Joseph also articulated a molecular mimicry theory, explaining that the adjuvant in the HPV vaccine caused Ms. Duncan's immune system to overreact and fight against her own cells. *Id.* at 3. In his opinion, this caused a significant aggravation of her PANDAS symptoms. *Id.* In December 2019, the Special Master held a status conference to discuss several deficiencies with Dr. Joseph's report. *See* Order to Show Cause at 3, ECF No. 97. Given these deficiencies and the "extended amount of time it took petitioner to submit [Dr. Joseph's] expert report," *id.* at 3, on February 24, 2020, the Special Master issued an Order to Show Cause why Ms. Duncan's petition should not be dismissed for failure to present "a credible, competent, and complete opinion in support of her claim that the HPV vaccination significantly aggravated her PANDAS," *id.* at 4.

After missing the deadline to respond to the show cause order, and then receiving a 60-day enlargement of time, Ms. Duncan submitted her response on July 20, 2020, arguing that her case should not be dismissed. Petr.'s Resp. to Ct.'s Feb. 24, 2020 Order to Show Cause, ECF No. 101. She also provided additional exhibits in support of her petition, including a supplemental report by Dr. Lyons-Weiler. Petr.'s Ex. 66 (Supplemental Report of Dr. Lyons-Weiler), ECF No. 102-8. She did not file a motion for a ruling on the record, as she indicated she would in her enlargement motion. Respondent filed a reply to Petitioner's response on August 24, 2020. Reply to Petr.'s Resp. to Order to Show Cause, ECF No. 105. The Special Master ordered Ms. Duncan to file any reply, as well as to "submit any material from Dr. Joseph as discussed in petitioner's

July 31, 2020 status report,” by no later than September 8, 2020. Order (Aug. 31, 2020) at 1, ECF No. 106. Ms. Duncan filed nothing in response to the order.

C. Special Master’s Decision

On October 19, 2020, the Special Master issued a decision denying Ms. Duncan compensation. The Special Master found that after four years Ms. Duncan had “not presented minimally competent evidence to substantiate her claim.” ECF No. 107 at 1.

The Special Master rejected each of Ms. Duncan’s procedural objections to the method of adjudication. First, he expressly disagreed with Ms. Duncan’s claim that the dismissal was imposed as a sanction. *Id.* at 5. Rather, the Special Master explained that Ms. Duncan’s claim was being dismissed because of the deficiencies in her experts’ reports. *Id.* Second, he disagreed with Ms. Duncan’s argument that the case should be resolved on summary judgment. *Id.* at 4–5. Citing binding precedent, he noted that a special master may “decide cases on written submissions *other* than motions for summary judgment.” *Id.* at 4 (quoting *Kreizenbeck v. Sec’y of HHS*, 945 F.3d 1362, 1365 (Fed. Cir. 2018) (emphasis in original)). The Special Master found that resolving Ms. Duncan’s case based on written submissions was appropriate because she was afforded a full and fair opportunity to present her case. *Id.* (quoting *Kreizenbeck*, 945 F.3d at 1366).

The Special Master then summarized the backgrounds and opinions of Ms. Duncan’s experts. *Id.* at 6–10. After evaluating each expert’s qualifications and the bases underlying their opinions, the Special Master found Dr. Lyons-Weiler unqualified to opine about causation because, among other things, he does not possess a medical license and does not appear to have performed research or published peer-reviewed work relevant to the issues in this matter. *Id.* at 10–11. The Special Master also took issue with Dr. Lyons-Weiler’s selective reliance upon the

affidavits of Ms. Duncan and her mother, rather than contemporaneous medical records, and his failure to review all the available information about Ms. Duncan. *Id.* at 11–12.

The Special Master expressed similar concerns regarding Dr. Joseph’s November 2019 report, which was based on a review of only certain parts of Ms. Duncan’s medical records and did not identify the bases for his assertions about Ms. Duncan’s medical history. *Id.* In addition, the Special Master found that, although qualified to opine on issues of chronic pediatric pain, Dr. Joseph either lacked or failed to disclose any specialized experience relevant to the issues in this matter, including in areas of immunology, molecular mimicry, and treating patients with PANDAS. *Id.* at 13.

Aside from the lack of qualifications, the Special Master also found the opinions expressed by Dr. Lyons-Weiler and Dr. Joseph unpersuasive. *Id.* More specifically, the Special Master found that the expert opinions were not sufficient to meet Ms. Duncan’s burden on two elements of proof: (1) the medical theory causally connecting the vaccine and alleged injury and (2) the timing of Ms. Duncan’s worsening symptoms. *Id.* at 14–16.

With respect to the former, the Special Master determined that the experts’ molecular mimicry theory was not sufficiently specific to Ms. Duncan’s case because it did not explain persuasively a connection between the HPV vaccine and PANDAS. *Id.* at 14. The Special Master acknowledged that medical literature submitted by Ms. Duncan indicated that strep infections can lead to PANDAS through the process of molecular mimicry, but Ms. Duncan’s experts did not identify any link between the molecular structures of strep bacteria and the HPV vaccine. *Id.* (citing Petr.’s Ex. 60 (PANDAS—Questions and Answers) at 2, ECF No. 102-2). Accordingly, he determined that the experts’ “bare assertion of molecular mimicry” did not establish Ms. Duncan’s burden of proof. *Id.* at 14.

With respect to timing, the Special Master found that Ms. Duncan did not establish that her PANDAS worsened in a “timeframe for which it is medically acceptable to infer causation.” *Id.* at 14–15 (citation omitted). The Special Master acknowledged Ms. Duncan’s experts’ opinion that adverse symptoms from an HPV vaccine would be expected to appear within zero to 365 days after the vaccination; however, he accepted “for sake of argument” a narrower timeframe of one to 20 days that “Ms. Duncan propose[d].” *Id.* at 15. The Special Master found that Ms. Duncan’s medical records did not document any worsening symptoms in the 20 days following her vaccination. *Id.* He explained that the only evidence of Ms. Duncan experiencing severe symptoms “‘within a few days’ of receiving the vaccination” came from the affidavits of Ms. Duncan and her mother, which were created three years after the events. *Id.* (citation omitted). In addition, the Special Master found that Dr. Lyons-Weiler and Dr. Joseph did not explain in their respective reports which symptoms Ms. Duncan allegedly suffered within a few days of the vaccination that they believe constituted a worsening of her PANDAS. *Id.* at 16. He concluded that Ms. Duncan, therefore, also did not produce reliable evidence on this element. *Id.*

Because she failed to submit persuasive evidence to meet her burden on at least two elements of proof, the Special Master dismissed Ms. Duncan’s case. *Id.* Ms. Duncan timely filed a motion for review. Petr.’s Mot. for Review, ECF No. 109

II. LEGAL STANDARDS

A. Standard of Review

This Court has jurisdiction to review a special master’s decision upon the timely request of either party. 42 U.S.C. § 300aa-12(e)(2). Under the Vaccine Act, a court deciding a motion for review may:

- (A) uphold the findings of fact and conclusions of law of the special master’s decision, (B) set aside any findings of fact and conclusions of law of the special master found to be

arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or (C) remand the petition to the special master for further action in accordance with the court's direction.

Id. § 300aa-12(e)(2)(A)–(C).

In conducting its review, the Court employs “a highly deferential standard.” *Hines v. Sec’y of HHS*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). “If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.” *Id.*; see *Hayman v. United States*, No. 02-725V, 2005 WL 6124101, at *2 (Fed. Cl. May 9, 2005) (decision should stand so long as the special master “consider[ed] all the relevant factors, ma[de] no clear error in judgment, and articulate[d] a rational connection between the facts found and the choice made”).

This “great deference” extends in particular to a special master’s findings of fact, which are reviewed under the arbitrary and capricious standard. *Munn v. Sec’y of HHS*, 970 F.2d 863, 870 & n.10 (Fed. Cir. 1992). On a motion for review, it is not the Court’s role “to reweigh the factual evidence;” rather, “the probative value of the evidence [and] the credibility of the witnesses . . . are all matters within the purview” of the special master as fact-finder. *Id.* at 871. Accordingly, the Court should not substitute its judgment for that of the special master even though it may have reached a different conclusion. *Johnson v. Sec’y of HHS*, 33 Fed. Cl. 712, 720 (1995).

B. Petitioner’s Burden of Proof for an Off-Table Significant Aggravation Claim

In an off-Table injury case, it is the petitioner’s burden to show, by a preponderance of the evidence, “that the vaccine was ‘not only a but-for cause of the [claimed] injury but also a substantial factor in bringing about the injury.’” *Moberly v. Sec’y of HHS*, 592 F.3d 1315, 1321–22 (Fed. Cir. 2010) (quoting *Shyface v. Sec’y of HHS*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); see 42 U.S.C. § 300aa-13(a)(1)(A). Where the injury alleged is a significant aggravation of a pre-

existing condition, the petitioner must prove causation by showing the six elements of proof set forth in *Loving v. Secretary of Health and Human Services*, 86 Fed. Cl. 135, 144 (2009), and adopted in *W.C. v. Secretary of Health and Human Services*, 704 F.3d 1352, 1357 (Fed. Cir. 2013).

These elements are:

(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 144.⁶

As relevant here, the petitioner’s medical theory must show that the vaccine at issue can cause the injury alleged. This requirement is satisfied by providing “a reputable medical or scientific explanation that pertains specifically to the petitioner’s case.” *Moberly*, 592 F.3d at 1322. “[T]he explanation need only be ‘legally probable, not medically or scientifically certain.’” *Id.* (quoting *Knudsen v. Sec’y of HHS*, 35 F.3d 543, 548–49 (Fed. Cir. 1994)). In addition, the petitioner must show “that the onset of symptoms occurred within a timeframe for which . . . it is medically acceptable to infer causation-in-fact.” *de Bazan v. Sec’y of HHS*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

Once the petitioner successfully establishes causation by a preponderance of the evidence, the burden shifts to the respondent to prove that factors unrelated to the vaccine were principally

⁶ The *Loving* factors combine the first three prongs of the four-prong test articulated in *Whitecotton v. Secretary of Health and Human Services*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), to evaluate an on-Table significant aggravation claim and the three-prong test announced in *Althen v. Secretary of Health and Human Services*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), to demonstrate causation in an off-Table injury case. *W.C.*, 704 F.3d at 1356, 1357.

responsible for the significant aggravation. *Knudsen*, 35 F.3d at 547; *see* 42 U.S.C. § 300a-13(a)(1)(B).

III. DISCUSSION

Petitioner's Motion raises four objections to the Special Master's decision, most of which address the procedural manner in which her petition was dismissed. Specifically, she alleges that the Special Master abused his discretion by: (1) dismissing her petition as a sanction, (2) not requiring Respondent to move for summary judgment and to submit rebuttal evidence, (3) failing to evaluate Ms. Duncan's evidence using a summary judgment standard of review, and (4) not giving appropriate weight to the opinion of her treating physician and for creating burdensome requirements for the physician's report. Having considered the parties' arguments, as well as the record in this case, the Court rejects Ms. Duncan's objections and declines to set aside the Special Master's decision.

A. The Special Master's Decision to Deny Compensation Was Not a Sanction.

In her first objection, Ms. Duncan contends that the Special Master abused his discretion by dismissing Ms. Duncan's case for "failure to prosecute and/or failure to comply with the court's orders." ECF No. 109 at 6 (quoting ECF No. 97 at 1). Relying on the language of the Order to Show Cause, Ms. Duncan characterizes the subsequent decision denying compensation as imposing a "sanction of dismissal," which she argues is reserved only for extreme cases involving circumstances not present here. *Id.* Respondent argues that the Special Master did not dismiss Petitioner's case as a sanction, but rather issued a comprehensive decision resolving her claim on the merits. Resp't.'s Mem. in Resp. to Petr.'s Mot. for Review at 11–12, ECF No. 111.

The decision denying compensation explicitly belies Ms. Duncan's claim. Directly addressing this argument, the Special Master explained that "the dismissal is not a consequence of

[Ms. Duncan] missing a deadline” or “punish[ment] for misconduct.” ECF No. 107 at 5 (“Although Ms. Duncan suggests that a dismissal with prejudice is a ‘sanction’ reserved for extreme cases, . . . the term ‘sanction’ fits this situation poorly, if at all.”). Rather, “[Ms. Duncan’s] case is being dismissed because her evidence is not adequate.” *Id.* The Special Master’s decision went on to evaluate the evidence Ms. Duncan presented and to determine that such evidence did not meet her burden on at least two elements of an off-Table significant aggravation claim. *Id.* at 6–16. Ms. Duncan has provided no reason for this Court not to take the decision at face value as an “evaluat[ion] based upon the evidence that [Ms. Duncan] has presented,” *id.* at 5, and to instead interpret the decision as a de facto sanction.⁷

Because the Special Master did not dismiss Ms. Duncan’s case as a sanction, this case is distinguishable from the cases on which Ms. Duncan relies. In *Simanski v. Secretary of Health and Human Services*, the United States Court of Appeals for the Federal Circuit held that a special master abused his discretion by dismissing a case as a sanction for the petitioner’s refusal to produce supplemental expert reports in response to court orders. 671 F.3d 1368, 1381 (Fed. Cir. 2012). The Court held that the orders at issue were couched in terms of providing the petitioners “the option” of supplementing the record. *Id.* at 1382. In such circumstance, the Court held that

⁷ At oral argument, Petitioner’s counsel seemed to concede that the Special Master dismissed Ms. Duncan’s claim on the merits, arguing that the Order to Show Cause and the denial decision applied different standards—the former involving a failure to prosecute and the latter involving a determination that Ms. Duncan’s evidence did not satisfy her burden. Hr’g Tr. at 8:10–13, ECF No. 117. He further argued that the “switch” in standard was procedurally unfair. *Id.* at 8:18–9:15. Petitioner’s counsel is correct that the Order at its outset directed Ms. Duncan to show cause why her case should not be dismissed for lack of prosecution or non-compliance with the Special Master’s orders. ECF No. 97 at 1. Although the show cause order could have been more clearly framed, the analysis section of the order gave Ms. Duncan sufficient notice that it was premised on the Special Master’s assessment that she had not submitted preponderant evidence, including “credible, competent, and complete opinion[s],” to carry her burden. *Id.* at 4.

“the special master should not have dismissed the petition for noncompliance with prior orders” when the petitioners had elected the option of resting on their submissions. *Id.*

In *Mocsek v. Secretary of Health and Human Services*, the Federal Circuit likewise held that dismissal of the petitioner’s claim for failure to comply with a court-ordered deadline was not warranted. 776 F. App’x 671, 674–75 (Fed. Cir. 2019). As in this case, the special master in *Mocsek* identified deficiencies in the petitioner’s expert reports and ordered her to file an additional expert report by a date certain. *Id.* at 673. After missing the deadline and failing to respond to an order to show cause, the case was dismissed for failure to prosecute and insufficient evidence. *Id.* The Court found that dismissal of the petition, “as opposed to some lesser sanction, . . . was an abuse of discretion” under the circumstances of the case. *Id.* at 674.

Here, Petitioner did not refuse or fail to file an expert report in response to an order, and the Special Master expressly stated that the dismissal was not a sanction. The Special Master considered Ms. Duncan’s evidence, including her expert reports, and determined on the merits that the evidence failed to carry her burden. Accordingly, the Court need not decide whether or not the particular events that transpired in the years leading up to the Special Master’s decision make this an “extreme case[],” ECF No. 109 at 2, in which the sanction of dismissal was appropriate.

B. The Special Master Did Not Abuse His Discretion by Not Requiring Respondent to File a Motion for Summary Judgment or Rebuttal Evidence.

Ms. Duncan next argues that the Special Master abused his discretion by dismissing her petition without requiring Respondent to move for summary judgment or file rebuttal evidence. *Id.* at 7. Respondent argues that the Special Master was permitted to rule on the parties’ written submissions, and that it was under no obligation to submit rebuttal evidence where Ms. Duncan, as the burdened party, had not established a *prima facie* case. ECF No. 111 at 13.

As Ms. Duncan correctly acknowledges, “the Vaccine Rules [do] not absolutely require . . . a motion for summary judgment.” ECF No. 109 at 7. Likewise, neither the rules nor the relevant precedent requires that Respondent produce rebuttal evidence in every case. *See Simanski*, 671 F.3d at 1379. Rather, in reviewing the method of adjudicating Ms. Duncan’s claim, the material inquiry is whether the Special Master “afford[ed] each party a full and fair opportunity to present its case and create a record sufficient to allow review of [his] decision.” *Kreizenbeck*, 945 F.3d at 1366 (quoting R. 3(b)(2), Rules of the U.S. Court of Federal Claims, app. B (“Vaccine Rules”)). Here, the Special Master provided such opportunity.

1. The Vaccine Rules Allow, But Do Not Require, Summary Judgment.

Consistent with Congress’s directives, the rules governing proceedings in Vaccine Act cases “provide for less-adversarial, expeditious, and informal . . . resolution of petitions,” including “the opportunity for summary judgment” and the “opportunity for parties to submit arguments and evidence on the record” without routine use of hearings. 42 U.S.C. § 300aa-12(d)(2)(A), (C), (D); *see* Vaccine R. 3(b)(2), 8(d). As relevant here, the Vaccine Rules provide that special masters may “decide a case on the basis of written submissions,” which “may include a motion for summary judgment,” “without conducting an evidentiary hearing.” Vaccine R. 8(d). Determining whether a hearing is necessary, or whether a case is suitable for a ruling on the record, lies within the “wide discretion” of the special masters. *Kreizenbeck*, 945 F.3d at 1365.

The text of the Vaccine Act and Vaccine Rules thus make clear that the parties have the option of filing a motion for summary judgment in a vaccine case, but neither authority can be construed to require Respondents to seek summary judgment. *Kreizenbeck* recently affirmed this interpretation, holding that “Rule 8(d) contemplates that special masters can decide cases on written submissions *other* than motions for summary judgment.” *Id.* at 1366 (emphasis in

original). In *Kreizenbeck*, the Federal Circuit rejected the petitioners' argument that, in light of their objection to a ruling on the record, the special master was obliged to either hold a hearing or resolve their case on summary judgment. *Id.* at 1365. As the Court explained, the language of the Vaccine Act does not "suggest[] a consent-based limitation on a special master's authority to rule on the record." *Id.* Rather, the Act requires only that the parties have the opportunity to "submit arguments and evidence on the record," *id.* (quoting 42 U.S.C. § 300aa-12(d)(2)(D)), and to seek summary judgment if appropriate, *id.* (citing 42 U.S.C. § 300aa-12(d)(2)(C)).

Although Ms. Duncan acknowledges *Kreizenbeck*, she suggests that *Simanski* is more instructive. ECF No. 109 at 7. As discussed above, *Simanski* reversed a special master's decision dismissing a petition for failure to comply with orders seeking supplemental expert reports where such orders were not expressly framed as directives. 671 F.3d at 1382. The Court's decision was further grounded on the fact that the respondent in *Simanski* had not yet filed a report under Vaccine Rule 4(c) setting forth its position on the petitioners' entitlement to compensation and had "indicated at several points that it intended to file a motion for summary judgment" arguing that the petitioners had not met their burden of proof. *Id.* at 1379. The Court noted that, "[i]n such a case, if the respondent believes the petitioner's evidence is insufficient to set forth facts that could justify a compensation award, the proper course is for the respondent to move for summary judgment." *Id.* at 1382.

Ms. Duncan appears to interpret *Simanski* as broadly requiring summary judgment in any case where the respondent disputes that a petitioner has met her burden. Such reading cannot be reconciled with the plain language of the rules and *Kreizenbeck*. Nor should the Court read the *Simanski* decision divorced from the context of that particular case, which—unlike the instant matter—was in an early procedural stage where the respondent had not responded at all to the

petitioner's claims. The Court in *Kreizenbeck* similarly described *Simanski* by reference to its procedural posture. *Kreizenbeck*, 945 F.3d at 1366 (“A party may seek summary judgment when, for example, they believe *at an early stage of the proceedings* that no material facts are in dispute and they will prevail as a matter of law,” *id.* (quoting *Simanski*, 671 F.3d at 1385) (emphasis added)). Because Respondent filed a Rule 4(c) report in this case and did not indicate an intention to move for summary judgment, the Court does not agree that *Simanski* is applicable here.

2. Respondent Is Not Required to Submit Rebuttal Evidence in All Cases.

The Vaccine Act employs a burden-shifting framework. 42 U.S.C. § 300aa-13(a)(1). Initially, Ms. Duncan, as the petitioner, has the affirmative duty to establish her entitlement to compensation by a preponderance of the evidence. *Id.* § 300aa-13(a)(1)(A). Only if she successfully establishes a *prima facie* case does the burden then shift to Respondent “to prove by a preponderance of the evidence that [Ms. Duncan’s] significant aggravation was caused by some factor other than the vaccine.” *Loving*, 86 Fed. Cl. at 144 (citing 42 U.S.C. § 300aa-13(a)(1)).

As is no less true in the context of other civil actions, the petitioner—as the party with the initial burden—can fail to establish a *prima facie* case for various reasons. The respondent may offer in rebuttal documents or testimony that undermine the petitioner’s evidence. *de Bazan*, 539 F.3d at 1353 (“The 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.”). Or, as is the case here, the respondent may simply argue that the petitioner’s evidence on its face is insufficient to carry her burden. *See Simanski*, 671 F.3d at 1379 (holding that special master could rule on the merits without the respondent filing evidence to contest the petition); *see also Prima Facie Case*, Black’s Law Dictionary 1441 (11th ed. 2019) (“[a] party’s production of enough evidence to allow the fact-trier to infer the fact at issue and rule in the party’s favor”).

Here, Respondent's position consistently has been that Ms. Duncan provided "insufficient evidence . . . regarding [her] claim of significant aggravation," and therefore the Special Master should deny compensation and dismiss the case. ECF No. 20 at 9; *see* ECF No. 105 at 3; ECF No. 111 at 2 n.2, 18. The Special Master ultimately agreed and, as discussed below, his decision should be upheld under this Court's deferential review. Because the Special Master determined that Ms. Duncan's evidence did not "carr[y] persuasiveness on elements [of her claim] for which she bears the burden of proof," ECF No. 107 at 16, the burden never shifted to Respondents. Thus, the Special Master did not abuse his discretion by denying compensation without requiring rebuttal evidence from Respondent.

3. Whether the Special Master Abused His Discretion by Ruling *Sua Sponte* on the Record.

Although special masters maintain broad authority in conducting proceedings, "[their] discretion to rule on the record is not without limitation." *Kreizenbeck*, 945 F.3d at 1366; *see Simanski*, 671 F.3d at 1385 ("authority may not be used in a way that deprives a party of procedural rights provided by the Vaccine Act and the Vaccine Rules"); *Jay v. Sec'y of HHS*, 998 F.3d 979, 983 (Fed. Cir. 1993) (resolving aspects of a vaccine case at an arbitrary point in the litigation raises due process concerns). The Special Master was required to provide Ms. Duncan with an adequate opportunity to present her case and develop the evidentiary record. *Kreizenbeck*, 945 F.3d at 1366 (quoting Vaccine R. 3(b)(2)). The record of the proceedings before the Special Master demonstrates that he did.

At its essence, Ms. Duncan's objection focuses on the fact that the Special Master, without alleged notice or awaiting a motion by either party, issued *sua sponte* a ruling on the record. ECF No. 109 at 7; Hr'g Tr. at 8:9–17, ECF No. 117. Neither party cited in the briefs a case in which a

special master disposed of a petition in circumstances analogous to this case.⁸ The Court located a recent case, *Porcello v. Secretary of Health and Human Services*, No. 17-1255V, 2020 WL 8672052 (Fed. Cl. Nov. 25, 2020), that provides a rough equivalent. In *Porcello*, the petitioner filed a motion for summary judgment, claiming that she had met her burden to demonstrate entitlement to compensation. *Id.* at *3. The respondent filed a response, arguing that her motion should be denied and the petition dismissed for insufficient evidence. *Id.* The special master issued an order not only denying summary judgment, but also denying compensation on the merits. *Id.* Like Ms. Duncan, the *Porcello* petitioner claimed that “dismissal of her claim in the face of no procedurally correct motion from Respondent seeking such relief is arbitrary and capricious and not in accordance with the law” and that, without notice of “the issues that the Special Master found probative in his ruling,” she “did not have a full and fair opportunity to develop and present her evidence and arguments.” *Id.* at *4 (citations omitted).

Acknowledging the “unusual” procedural path of the case, *Porcello* held that the special master did not abuse his discretion by ruling on the record in the manner he did. *Id.* at *5. The

⁸ The Court noted this fact at the hearing on Petitioner’s Motion and allowed both parties the opportunity to supplement the record with any additional citations to procedurally analogous cases. ECF No. 117 at 73:9–24. Respondent filed a response citing five cases. Resp’t.’s Resp. to Ct.’s Inquiry Regarding Applicable Cases, ECF No. 115. These cases are not exactly on point. *See, e.g., Padmanabhan v. Sec’y of HHS*, 638 F. App’x 1013, 1014 (Fed. Cir. 2016) (dismissal under Vaccine Rule 21 for failure to prosecute); *Seid v. Sec’y of HHS*, No. 17-604V, 2019 WL 1504371, at *1 (Fed. Cl. Spec. Mstr. Mar. 4, 2019) (dismissal after the petitioner moved for a ruling on the record); *Wanless v. Sec’y of HHS*, No. 05-286V, 2005 WL 6120650, at *1 (Fed. Cl. Spec. Mstr. Sept. 29, 2005) (dismissal after counsel represented that the petitioner would be dismissing for inability to obtain expert report). Petitioner filed a notice citing one case. Petr.’s Notice of Filing Ex. #68, ECF No. 118. Although the *sua sponte* ruling in that case gets closer to the circumstances here, the reasons it was set aside are inapplicable. *Campbell v. Sec’y of HHS*, 69 Fed. Cl. 775, 780–83 (2006) (holding that special master denied petitioners a full and fair opportunity to present case where the record contained factual disagreements and ambiguities that should have been explored at evidentiary hearing and where special master relied on medical articles she introduced into the record shortly before ruling).

petitioner “had multiple opportunities to provide evidentiary and affidavit support for her claim, all of which she took advantage,” and remanding for another “opportunity to present her case in a different way” with “already-admitted evidence” would not likely alter the decision. *Id.*

This Court reaches a similar conclusion. Over the course of years, the Special Master afforded Ms. Duncan numerous opportunities to submit preponderant evidence establishing that the HPV vaccine caused a significant aggravation of her PANDAS symptoms, including multiple extensions of time to file outstanding medical records and expert reports. *See, e.g.*, Order (Dec. 5, 2016), ECF No. 13; Order (Sept. 25, 2017), ECF No. 54; Order (Aug. 1, 2019), ECF No. 89; Order (Aug. 19, 2019), ECF No. 91; Order (Oct. 3, 2019), ECF No. 95. To be certain, the record reflects Ms. Duncan’s difficulties in obtaining expert reports. *See, e.g.*, Status Report of Petr. (Nov. 7, 2017), ECF No. 55. Eventually, however, she submitted such reports and developed a broad record including, *inter alia*, four affidavits in total from her and her mother; 24 exhibits containing medical, school, and other records; four reports in total submitted by two experts; and 25 medical articles or other literature. *See* Petr.’s Notice of Filing Ex. & Am. Ex. List, ECF No. 96; *see also* Petr.’s Notice of Filing Ex. #59-67, ECF No. 102.

Notwithstanding the quantity of materials submitted in support of her petition, the Special Master on numerous occasions explained to Ms. Duncan the inadequacies in her evidence. *See, e.g.*, Order (Sept. 24, 2018), ECF No. 77 (noting that reports from experts without medical degrees are uncommon); Order (Feb. 22, 2019), ECF No. 79 (noting several deficiencies in Dr. Lyons-Weiler’s report and identifying an unflattering article about the expert); ECF No. 97 at 3 (noting deficiencies in Dr. Joseph’s report). He also warned Ms. Duncan at least once before issuing the Order to Show Cause that her failure to timely cure the inadequacies could result in dismissal. ECF No. 77 at 1.

After over three years of litigation, the Special Master issued an Order to Show Cause in February 2020. He allowed Ms. Duncan almost five months to respond, including granting Ms. Duncan's request for an extension of time to file a response, any remaining evidence, and a motion for a ruling on the record. Order (May 20, 2020), ECF No. 100. The Special Master also provided Ms. Duncan the opportunity to file a reply to Respondent's response to the show cause order, as well as to submit additional materials from Dr. Joseph. Order (Aug. 31, 2020) at 1, ECF No. 106. Ms. Duncan did not take advantage of this opportunity, and the Special Master issued his decision in October 2020.

Given these facts, the Special Master did not abuse his discretion in determining that Ms. Duncan had full and fair occasion to offer evidence and arguments in support of her case. *See Kreizenbeck*, 945 F.3d at 1366; *see also Porcello*, 2020 WL 8672052 at *5. Additionally, the record Ms. Duncan developed is comprehensive and allows the Court to sufficiently review the Special Master's decision. *See Kreizenbeck*, 945 F.3d at 1366. As in *Porcello*, the Court does not see how remanding the case to the Special Master to allow for a more typical procedure—like motions for a ruling on the record—would likely result in a different outcome.⁹ *See Porcello*, 2020 WL 8672052 at *5. The Special Master evaluated the credibility and persuasiveness of Ms. Duncan's already-submitted evidence, most importantly her experts' opinions, and his weighing of that evidence was within his discretion.

⁹ The parties agreed at oral argument that remand would be the appropriate remedy in the event the Court does not uphold the Special Master's decision. ECF No. 117 at 53:13–19, 70:11–16. Petitioner's counsel indicated that, if remanded, he would file any remaining evidence Ms. Duncan had to offer and a motion for a ruling on the record. *Id.* at 61:8–18, 70:11–16.

C. The Special Master Did Not Apply an Erroneous Standard of Review.

Because the Special Master was not required to resolve Ms. Duncan’s case on summary judgment, he did not commit any error by not applying the summary judgment standard. Rather, the Special Master appropriately weighed Ms. Duncan’s evidence against the governing legal standard. Applying the deferential review afforded to his decision, the Court finds, with one exception that does not warrant remand, that the Special Master’s findings were not arbitrary and capricious.

1. The Special Master Applied the Appropriate Standard of Review.

Ms. Duncan contends that “[w]hen a petition is decided on the merits, the special [m]aster must view the evidence in [the] light most favorable to the petitioner, draw all reasonable inferences in petitioner’s favor, and resolve all doubt over factual issues in favor of petitioner.” ECF No. 109 at 8 (citation omitted). She claims that the Special Master’s decision should be reversed because he did not utilize the proper standard. *Id.* As Respondent correctly observes, ECF No. 111 at 14, each of the cases Ms. Duncan relies on to support the familiar summary judgment standard involved appeals from orders on motions for summary judgment. *See* ECF No. 109 at 6. Ms. Duncan does not provide a rationale for applying this more favorable standard where a special master decides a case, as he is permitted to do, “on written submissions *other* than motions for summary judgment.” *Kreizenbeck*, 945 F.3d at 1366 (emphasis in original).

To the contrary, when a special master decides a case on the merits his statutorily defined role requires that he make findings of fact based on his assessment of the evidence and conclusions of whether such evidence satisfies the preponderance standard with respect to the parties’ claims. *See* 42 U.S.C. §§ 300aa-12(d), -13; *see also* Vaccine R. 3(b)(1). Indeed, “Congress envisioned that the special masters would become specialists in vaccine-related injuries and would use ‘their

accumulated expertise in the field [to] judg[e] the merits of the individual claims.” *Simanski*, 671 F.3d at 1371 (citation omitted). For that reason, this Court employs a “uniquely deferential” review of special master decisions and is directed not to “second guess the Special Masters fact-intensive conclusions.” *Hodges v. Sec’y of HHS*, 9 F.3d 958, 961 (Fed. Cir. 1993) (the special master’s resolution of a vaccine case “is essentially a judicial process”); *see* 42 U.S.C. § 300aa-12(e)(2).

Thus, the Court finds no error in the standard applied by the Special Master in reviewing Ms. Duncan’s evidence, which appropriately assessed the weight of her evidence rather than presuming the facts in Ms. Duncan’s favor.

2. The Special Master’s Findings Were Not Arbitrary and Capricious.

Utilizing the deferential arbitrary-and-capricious standard of review, the Court finds that Ms. Duncan has not demonstrated that the Special Master’s decision should be set aside. Ms. Duncan argues that the Special Master based his decision on a perceived lack of qualifications of her experts and a selective view of her evidence. ECF No. 109 at 10, 11. Respondent argues that the Special Master’s findings were “rational, based on the record, [and] in accordance with the law.” ECF No. 111 at 11. With one exception, the Court agrees with Respondent.

First, the Special Master determined that “based strictly on qualifications,” Ms. Duncan’s experts did not “present a minimally credible case” that the HPV vaccine significantly aggravated Ms. Duncan’s PANDAS. ECF No. 107 at 13. The decision described several reasons underlying this finding. For example, the Special Master noted that, despite opining on the expected course of Ms. Duncan’s PANDAS, Dr. Lyons-Weiler is not a medical doctor. *Id.* at 10. He has a Ph.D. in Ecology, Evolution and Conservation Biology, a master’s degree in Zoology, and a bachelor’s degree in Biology. *Id.* at 7, 11; *see* ECF No. 78 at 1. Dr. Lyons-Weiler did not indicate in his report or curriculum vitae any experience studying or researching PANDAS or working with

PANDAS patients. ECF No. 107 at 10. He also has been found by special masters in other vaccine cases as unqualified to opine on vaccine causation issues. *Id.* at 11 (citing *A.S. v. Sec’y of HHS*, No. 16-551V, 2019 WL 5098964, at *11 (Fed. Cl. Spec. Mstr. Aug. 27, 2019); *Kamppi v. Sec’y of HHS*, No. 15-1013V, 2019 WL 5483161, at *11 (Fed. Cl. Spec. Mstr. July 24, 2019)). The Special Master explained that Dr. Joseph, although well qualified to opine on issues in his area of practice, has no specialized experience in immunology and no background in studying or researching molecular mimicry, nor did he indicate any degree of experience treating PANDAS. *Id.* at 13. Moreover, the Special Master found that the reliability of both experts’ opinions was reduced by the fact that they reviewed a very limited number of the relevant records. *Id.* at 12.

These findings bear on the Special Master’s assessment of the credibility of Ms. Duncan’s experts and the reliability of their testimony—matters that he was permitted and, in fact, expected to consider as factfinder. *See Porter v. Sec’y of HHS*, 663 F.3d 1242, 1250–51 (Fed. Cir. 2011); *see also Moberly*, 592 F.3d at 1325–26. The Court sees no reason to disturb his determination, which was both rationally explained and supported by record evidence.

Second, the Special Master found that Ms. Duncan failed to establish *Loving* prong 4 because her medical theory was merely a “bare assertion[] of molecular mimicry” unconnected to the specific facts of her case. ECF No. 107 at 14. Ms. Duncan argues that this “is not an accurate reflection of the evidence,” claiming that the reports of Dr. Lyons-Weiler and Dr. Joseph explained how the vaccine through the process of molecular mimicry caused Ms. Duncan’s immune system to attack itself and thus aggravate her PANDAS symptoms. ECF No. 109 at 10. That explanation, if it exists, is not directly apparent to this Court.

To be sure, both experts broadly explained the theory of molecular mimicry and generally opined that it provides the causal link between the HPV vaccine and Ms. Duncan’s aggravated

PANDAS symptoms. *See* ECF No. 78 at 5; *see also* ECF No. 96-1 at 3. But neither expert's molecular-mimicry explanation provided a specific link between the HPV vaccine and PANDAS. At best, the experts appear to deduce that PANDAS, as an autoimmune disorder, can be caused by the HPV vaccine because the HPV vaccine contains an adjuvant and adjuvants can cause autoimmunity. *See* ECF No. 78 at 4–5; *see also* ECF No. 96-1 at 3. Such explanation could apply equally to any case involving an adjuvanted vaccine and an alleged injury relating to an autoimmune disorder or disease. *See Caves v. Sec'y of HHS*, 100 Fed. Cl. 119, 135 (2011) (“there is an important difference between the general theory of molecular mimicry . . . and the more specific theory that the . . . vaccine [at issue] is capable of triggering an autoimmune response that culminates in the [petitioner's injury]”).

Both experts highlighted Ms. Duncan's history of strep-A infections as making her predisposed to molecular mimicry. *See* ECF No. 78 at 5; *see also* ECF No. 96-1 at 3. Ms. Duncan further relied on medical literature explaining that PANDAS is caused when a child's immune system attacks healthy molecular structures that are being mimicked by the molecular structure of the strep bacteria. ECF No. 101 at 6 (citing Petr.'s Ex. 60 (ECF No. 102-2)). As the Special Master noted, however, the cited PANDAS article does not discuss the HPV vaccine, and neither expert attempted to draw similarities between the molecular structures of strep and the HPV vaccine. ECF No. 107 at 14. Thus, the Special Master did not act arbitrarily and capriciously in finding that Ms. Duncan's experts did not provide a medical theory sufficient to establish *Loving* prong 4.

Third, the Special Master concluded that Ms. Duncan's experts neglected to “identif[y] the specific ways in which her PANDAS became worse.” *Id.* at 16. Ms. Duncan disagrees, arguing that the Special Master did not consider evidence that Ms. Duncan experienced severe symptoms

within a few days of receiving the vaccine. ECF No. 109 at 10 (citing Ms. Duncan's affidavit (ECF No. 1-2)). The decision shows that the Special Master considered such evidence and, considering the evidence as a whole, determined that it carried less weight. He explained that the affidavits drafted by Ms. Duncan and her mother for purposes of this litigation were the only evidence she submitted to establish symptoms occurring near the date of her vaccination. ECF No. 107 at 15. The affidavits' recounting of Ms. Duncan's symptoms, however, was not corroborated by the medical records created around the time of her vaccination. *Id.* The Special Master also noted other inconsistencies with record evidence that put into question the accuracy of the assertions in the affidavits. *Id.* at 11 (comparing statements that Ms. Duncan was a "straight A" student with school records showing poor academic performance in the year before Ms. Duncan received the vaccine). The Special Master's assessments were well within his discretion. Because her experts appear to have simply accepted Ms. Duncan's account of her symptoms as the basis for their conclusions, they are reasonably subject to the same criticism. *See Burns v. Sec'y of HHS*, 3 F.3d 415, 417 (Fed. Cir. 1993) (finding "special master did not err in accepting the contemporaneous medical records over the testimony of fact witnesses" and rejecting expert opinion based on facts not substantiated by the record).

Moreover, as the Special Master observed, the experts did little more than list the symptoms Ms. Duncan has experienced since she received the vaccine and provide a conclusory opinion that such symptoms constitute a significant aggravation of her pre-existing PANDAS condition. *See* ECF No. 96-1 at 2, 4; *see also* ECF No. 78 at 4. Neither expert explained based on medical expertise whether these symptoms were associated with Ms. Duncan's PANDAS and, if so, whether they represented new or worsened symptoms.

Finally, the Special Master found that Ms. Duncan failed under *Loving* prong 6 to show that aggravated PANDAS symptoms occurred within one to 20 days of her receiving the vaccine. ECF No. 107 at 15. Ms. Duncan claims that, in making this determination, the Special Master disregarded her experts' opinion that adverse symptoms could occur within zero to 365 days after an HPV vaccination. ECF No. 109 at 10. On this point, Ms. Duncan is correct.

The Special Master acknowledged the 365-day timeframe asserted by Ms. Duncan's experts but stated that Ms. Duncan "propose[d] a narrower span" of 20 days or less. ECF No. 107 at 15 (citing Petr.'s Ex. 67 ("Severe somatoform and dysautonomic syndromes after HPV vaccination: case series and review of literature"), ECF No. 102-9). The study to which the Special Master referred involved 18 girls aged 12 to 24 who complained of symptoms appearing one to 20 days after receiving the HPV vaccination. ECF No. 102-9 at 1. As a threshold matter, Ms. Duncan cited this study in her response to the Special Master's show cause order to demonstrate the "logical sequence" element (*Loving* prong 5) of her claim. ECF No. 101 at 7. She did not propose the study as an alternative to her experts' opinion. Indeed, after discussing the study, Ms. Duncan specifically referenced her experts' opinion that 365-days is the proper timeframe. *Id.*

"[F]or the sake of argument," however, the Special Master accepted the shorter range.¹⁰ ECF No. 107 at 15. By doing so, he never assessed or determined whether the experts' significantly longer suggestion of zero to 365 days was appropriate. *See Koehn v. Sec'y of HHS*, 773 F.3d 1239, 1244 (Fed. Cir. 2014). This omission is potentially material to the *Loving* prong 6 analysis because, although the Special Master reasonably found that Ms. Duncan did not demonstrate by a preponderance of evidence that her PANDAS symptoms worsened within 20

¹⁰ In this Court's experience, when one assumes facts or arguments *arguendo*, one typically accepts the facts or arguments most favorable to the proponent, which in this case would be the longer timeframe.

days of her vaccination, the record contains evidence of later-appearing symptoms within 365 days. *See* ECF No. 107 at 15 (discussing January 14, 2014 medical record that documents Ms. Duncan’s complaint of “bee stings all over [her] body, fatigue, chest pain, and anxiety” and expert testimony opining that Ms. Duncan’s symptoms “escalated severely in early 2014”) (citations omitted). Because he disregarded without any rational explanation Ms. Duncan’s expert testimony identifying a more generous timeframe, the Special Master’s finding that Ms. Duncan did not establish the “timing” prong was arbitrary and capricious. *See Johnson*, 33 Fed. Cl. at 727 (finding special master erred by totally disregarding and ignoring expert testimony in the record).

Ultimately, however, this error does not warrant setting aside the decision because the “timing” prong was not the only ground for dismissal in this case. *See* ECF No. 107 at 16. As discussed above, the Special Master’s finding that Ms. Duncan failed under *Loving* prong 4 to establish a persuasive medical theory connecting the HPV vaccine to an aggravation of PANDAS was not arbitrary or capricious. Thus, he had sufficient basis to deny her claim. *See Koehn*, 773 F.3d at 1244 (failure to meet burden under any one of the *Althen* prongs is dispositive).

D. The Special Master Did Not Abuse His Discretion in Assessing the Weight of Dr. Joseph’s Opinion or by Imposing Burdensome Expert Report Requirements.

Finally, Ms. Duncan asserts that the Special Master impermissibly “disregarded and/or downplayed the opinion” of her treating physician, Dr. Joseph, and “created requirements [for expert reports] which were unduly burdensome to a treating physician.” ECF No. 109 at 11. Considering the record as a whole, the Court rejects this objection.

1. The Special Master’s Evaluation of Dr. Joseph’s Opinion

The Federal Circuit has explained that, in addition to medical records, “medical opinion testimony [is] 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.” *Capizzano v. Sec’y of HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (citation omitted). The Act, however, also expressly specifies that any “diagnosis, conclusion, [medical] judgment, test result, report, or summary” relevant to “the nature, causation, and aggravation” of a petitioner’s injury “shall not be binding on the special master or court.” 42 U.S.C. § 300aa-13(b)(1). Rather, it is the duty of the special master to consider the record as a whole and evaluate the “weight to be afforded to any such [evidence].” *Id.* In “[w]eighing the persuasiveness of particular evidence,” including expert opinions, the special master is expected “to assess the reliability of [the] testimony.” *Moberly*, 592 F.3d at 1325. This assessment “often turn[s] on credibility determinations, particularly in cases . . . where there is little supporting evidence for the expert’s opinion.” *Id.* at 1325–26. A special master’s findings as to credibility of an expert witness and the persuasiveness of his medical theories are “virtually unchallengeable on appeal.” *Lampe v. Sec’y of HHS*, 219 F.3d 1357, 1362 (Fed. Cir. 2000) (“That level of deference is especially apt in a case in which the medical evidence of causation is in dispute,” *id.* (quoting *Hodges*, 9 F.3d at 961)).

Ms. Duncan’s final objection does not specifically challenge any particular findings with respect to Dr. Joseph’s opinion. Instead, she alleges generally that the Special Master did not give Dr. Joseph’s report “the proper weight to be afforded to a treating physician under the Vaccine Act.” ECF No. 109 at 12. The Special Master, however, was not bound under the Act to accept Dr. Joseph’s opinion without inquiring into its credibility and reliability. *See* 42 U.S.C. § 300aa-13(b)(1); *see also Moberly*, 592 F.3d at 1325. Ms. Duncan’s mere disagreement with the evidentiary weight assigned by the Special Master to Dr. Joseph’s testimony is not sufficient to overturn his finding. *See Lampe*, 219 F.3d at 1362.

As the decision demonstrates, the Special Master evaluated Dr. Joseph's opinion that the HPV vaccine significantly aggravated Ms. Duncan's PANDAS. He summarized the substance of Dr. Joseph's reports, reviewed Dr. Joseph's professional qualifications, and articulated several reasons why he found Dr. Joseph to be unqualified to opine on the relevant medical theory at issue in this case and, in any event, why his opinion was unpersuasive. ECF No. 107 at 6–7, 9–10, 12–13, 14–16. These reasons included, *inter alia*, that: (1) Dr. Joseph did not begin treating Ms. Duncan until almost two-and-one-half years after she received the HPV vaccine, *id.* at 12; (2) it was not until six months after Dr. Joseph began seeing Ms. Duncan that his records first mention the HPV vaccine, documenting only Ms. Duncan's belief that her symptoms significantly worsened after the vaccination, *id.* (citation omitted); (3) Dr. Joseph's records (which are current through December 2016) do not reflect his conclusion that the HPV vaccine affected Ms. Duncan's condition, *id.*; (4) he did not specifically identify when Ms. Duncan experienced significantly aggravated PANDAS symptoms, what those symptoms were, or the basis for his assertions, *id.* at 9–10; and (5) he appeared simply to have adopted Dr. Lyons-Weiler's explanation of the medical theory purportedly connecting the HPV vaccine to an aggravation of PANDAS, *id.* at 9, 13.

Because the Special Master “clearly articulated why he declined to afford significant weight” to Dr. Joseph's medical opinion, and such explanation is both reasoned and supported by the record, the Court finds that the Special Master acted within his discretion in assessing this evidence. *See Cedillo v. Sec'y of HHS*, 617 F.3d 1328, 1348 (Fed. Cir. 2010) (no error in treatment of evidence from treating physicians); *see also Moberly*, 592 F.3d at 1325–26 (same); *Holmes v. Sec'y of HHS*, 115 Fed. Cl. 469, 489 (2014) (special master did not abuse discretion in evaluating opinions of treating physicians).

2. The Special Master's Instructions to Witnesses Offering Opinion Testimony

Ms. Duncan also argues that the Special Master's eight-page order setting forth instructions for expert reports were unduly burdensome for treating physicians. ECF No. 109 at 11. Ms. Duncan claims that Dr. Joseph, as a treating physician, should not have been expected to review voluminous medical records, cite medical articles, or take other steps to support his opinion in ways one would expect of a retained expert. *Id.* She contends that the Special Master's order made it difficult to obtain a written opinion meeting the criteria of the instructions. *Id.*

In his decision, the Special Master framed the instructions as guidelines. He explained that the purpose of the instructions was to "assist Ms. Duncan and her attorney" by "guid[ing] any expert in the presentation of reports."¹¹ ECF No. 107 at 2; *see* ECF No. 97 at 2 (explaining that the Special Master "proposed instructions to guide the parties' expert reports"); *see also* Order Regarding Petr.'s Comments on Expert Instructions at 1, ECF No. 51 ("The instructions are drafted to help the parties, particularly the petitioner, to present evidence on all relevant topics."). Although the Special Master expected treating physicians to follow with the instructions, he clarified that he would still consider any expert submission even if it was not in strict compliance. ECF No. 51 at 1. He warned, however, that "a relatively conclusory statement from a treating doctor may not be given much evidentiary weight."¹² *Id.*

¹¹ Despite being provided with the proposed instructions and the opportunity to comment, Ms. Duncan did not object prior to the instructions becoming final. *See* Order (July 21, 2017), ECF No. 48. Instead, after the final instructions issued, Ms. Duncan sought clarification about whether they applied to treating physicians. Petr.'s Resp. Ct.'s Orders of 7/21/17 & 8/8/17 Regarding Expert Report Instructions at 1-2, ECF No. 50.

¹² The instructions take a relatively stronger tone on the effect of non-compliance, noting that "the topics listed below constitute the minimum content for an expert's report" and that failure of the expert to address all the topics may result in the expert being "directed to write a supplemental report." ECF No. 49 at 3 n.1.

Regardless of whether the instructions set forth requirements or only suggestions, Ms. Duncan's point is not without some merit. The level of specificity detailed in the Special Master's instructions, which cover eight topics containing around 30 sub-topics, could likely be "very intimidating to [a] treating physician," ECF No. 50 at 2, who as Ms. Duncan points out may not charge an hourly fee to draft an opinion letter on behalf of a patient, ECF No. 109 at 11. As the Federal Circuit has explained, "[t]he Vaccine Act does not contemplate full blown tort litigation." *Knudsen*, 35 F.3d at 549. Rather, it "established a federal 'compensation program' under which awards are to be 'made to vaccine-injured persons quickly, easily, and with certainty and generosity.' The program is supposed to be 'fair, simple, and easy to administer.'" *Id.* (internal citations omitted). The Court has therefore cautioned against imposing requirements on expert testimony that hinder "the purpose and nature of the . . . program," *id.*, or "impermissibly raise[] a claimant's burden under the Vaccine Act," *Capizzano*, 440 F.3d at 1325.

Nevertheless, Ms. Duncan recognizes that expert testimony, as with any evidence, "must be reliable and probative." ECF No. 109 at 11. The Vaccine Act and the Vaccine Rules grant special masters "broad authority in conducting proceedings under the Act, including full control over discovery and the power to require the production of evidence and information." *Simanski*, 671 F.3d at 1371 (citing 42 U.S.C. § 300aa-12(d)(3); Vaccine R. 3(a), 7(a), 8(c)). This is no less true with respect to expert opinions. *See Moberly*, 592 F.3d at 1324 ("[T]he special master is entitled to require some indicia of reliability to support the assertion of the expert witness."); *see also Ryman v. Sec'y of HHS*, 65 Fed. Cl. 35, 40-41 (2005) (special master acts as both a "gate-keeper" to determine whether expert testimony should be admitted, credited, and relied on and "a trier-of-fact [who] therefore may properly consider the credibility and applicability of medical theories").

Here, the Court need not determine whether the expert instructions in general improperly crossed the boundary between a proper exercise of the Special Master's gate-keeper/trier-of-fact function and an improper heightening of Ms. Duncan's burden. Ms. Duncan does not argue that the instructions altered her burden or were inconsistent with the Federal Circuit's precedent regarding the elements of a *prima facie* significant aggravation claim. *See* ECF No. 51 at 1. Moreover, the Special Master's decision to deny compensation was not based on mere non-compliance with some technical aspect of the expert instructions. Setting aside the instructions altogether, the reasons why the Special Master decided not to credit Dr. Joseph's opinion were rational, clearly articulated, and supported by the record.

Ms. Duncan's chief complaint appears to be that the Special Master should not have required Dr. Joseph to review the "thousands [of] medical records in this case." ECF No. 109 at 11. The instructions, however, did not contain such requirement. *See* ECF No. 49 at 3 (requiring under the "Review of Materials" topic only that an expert identify all the materials he considered, but not specifying what materials must be reviewed). That the Special Master found Dr. Joseph's opinion unpersuasive because Dr. Joseph reviewed only a limited number of medical records is not unreasonable under the particular circumstances of this case. Dr. Joseph did not begin treating Ms. Duncan until years after she received the vaccination. ECF No. 107 at 12; *see* ECF No. 26-1 at 11. His own records submitted by Ms. Duncan do not reflect his opinion that the HPV vaccine significantly worsened Ms. Duncan's PANDAS. *See generally* ECF No. 26-1. The Court sees no error in the Special Master's decision not to afford significant weight to Dr. Joseph's medical opinion about the cause of Ms. Duncan's allegedly worsened condition when he did not review medical records documenting Ms. Duncan's condition before her vaccination (except one record

