In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

* *		
KASEY COTTINGHAM,	*	
	*	No. 15-1291V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	
	*	Filed: September 27, 2021
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	attorneys' fees and costs, reasonable
	*	basis, remand
Respondent.	*	
* *		

Andrew D. Downing, Van Cott & Talamante, PLLC, Phoenix, AZ, for petitioner; Voris Johnson, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING ATTORNEYS' FEES AND COSTS[1]

An October 30, 2015 petition alleged that the human papillomavirus ("HPV") vaccine harmed Kasey Cottingham and sought relief pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10 through 34 (2012). However, the case was dismissed within a year of its filing. Cottingham v. Sec'y of Health & Human Servs., No. 15-1291V, 2016 WL 6575170 (Fed. Cl. Spec. Mstr. Oct. 13, 2016).

Although Ms. Cottingham did not receive compensation, she is requesting an award of attorneys' fees and costs as permitted by the Vaccine Act. 42 U.S.C. § 300aa–15(e). After three rounds of adjudications in both the Office of Special Masters and the Court of Federal Claims, as well as a fourth round of adjudication

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

as a result of a remand from the Federal Circuit, the Court of Federal Claims has remanded the case for an additional (fifth) review of evidence that might support a finding of reasonable basis. Because she has failed to meet this predicate showing, Ms. Cottingham is not eligible for an award of attorneys' fees and costs. Therefore, her motion is denied.

I. Background[2]

The series of events about Ms. Cottingham's health is set out in section A, below. The history of her claim through the Decision Dismissing Case is discussed in section B, below. The lengthy history of decisions and appellate opinions regarding the still pending motion for attorneys' fees and costs is presented in section C, below.

A. Medical Chronology

Ms. Cottingham was born in 1998. Her health through 2011 was relatively routine and overall good.

In March 2012, a doctor at the Middle Creek Urgent Care facility diagnosed Ms. Cottingham with mononucleosis. A week later, Ms. Cottingham's regular pediatrician saw her. Ms. Cottingham stated that her throat was hurting, she felt tired, and she had headaches. The doctor diagnosed her as having a viral illness on top of the mononucleosis. Exhibit 3 at 55-56.

Before starting high school, Ms. Cottingham returned to the pediatrician's office. The doctor did not record any significant health concerns. During this appointment, which occurred on July 5, 2012, Ms. Cottingham received three vaccinations – the hepatitis A vaccine, the meningococcal conjugate vaccine, and the HPV vaccine. More specifically, Ms. Cottingham received the "quadrivalent" HPV vaccine. Exhibit 3 at 99-100. Ms. Cottingham's claim in the Vaccine Program rested upon the HPV vaccine.

Approximately one month later, while performing as a majorette in her school's band, Ms. Cottingham twisted her right knee. The pediatrician recorded that except for the problem with her right knee, a review of symptoms was

[2] Substantial portions of the present decision repeat material in the January 7, 2021 decision because the Court vacated the January 7, 2021 decision and, thus, the information needs to be stated again in the present decision. See Cottingham v. Sec'y of Health & Human Servs., 971 F.3d 1337, 1345 n. 2 (Fed. Cir. 2020) ("we review only the [most recent] decision").

"negative." Exhibit 3 at 64. For the knee injury, Ms. Cottingham went to physical therapy. Exhibit 5.

On October 10, 2012, Ms. Cottingham went to the Children's Hospital of Alabama where she saw a pediatric gynecologist. The history of present illness from this visit states:

> She has periods that are monthly. Sometimes there are 2 weeks in between and sometimes they are a full month in between. When they do occur she does have to wear double protection on her for a few days because of the menorrhagia. Her periods last for about 2 days and they are off for about 2 days and they come back for about 4-5 days.

Exhibit 9 at 4. Except as noted in the history of present illness, the doctor's review of symptoms was "negative times 10." Id. The gynecologist prescribed oral contraception to control Ms. Cottingham's monthly cycle.

According to an affidavit Ms. Cottingham signed for this litigation, her health changed on November 1, 2012 (almost four months after her receipt of the HPV vaccination). Ms. Cottingham stated: "I began getting regular weekly headaches. Over the next few weeks, not only did the frequency of headaches increase but I also began to experience episodes of near black-outs where my vision became temporarily impaired." Exhibit 1 ¶ 5. Ms. Cottingham's attorney asserted that November 1, 2012, marked the onset of the problems the HPV vaccine allegedly caused in Ms. Cottingham. Pet'r's Mot. for Attorneys' Fees and Costs, filed Oct. 26, 2016, at 5.

On November 30, 2012, Ms. Cottingham returned to her pediatrician's office. She complained about having a fever, yellow mucous, a sore throat in the mornings, and headaches "off and [on] all week." The doctor diagnosed her as having "acute sinusitis." Exhibit 3 at 87-88. Ms. Cottingham's affidavit stated that during the November 30, 2012 appointment, she told her doctor about her "symptoms" without specifying what those symptoms were. The affidavit also recounts that the doctor prescribed an antibiotic and recommended that she drink plenty of water. Exhibit 1 ¶ 6. The doctor's November 30, 2012 note did not characterize the headaches as ongoing or chronic.

According to Ms. Cottingham's affidavit, her "headaches, low-grade fevers and near black-outs continued." In addition, during practices for majorettes, Ms.

Cottingham "need[ed] to stop because [she] was feeling dizzy." Nevertheless, Ms. Cottingham "didn't want to complain because [she] was taught to tough out what [she] thought was a temporary condition." Id. ¶¶ 7-8.

Approximately two months later, Ms. Cottingham had another appointment with her pediatrician. The history of present illness states that Ms. Cottingham

> comes in today with 2 days of runny nose and congestion. Today she's had low-grade fever of 100.4, she has also had [a] sore throat along with runny nose and congestion. Has had a headache today as well. No cough, increased work of breathing or shortness of breath. No vomiting or diarrhea.

Exhibit 3 at 78 (record created Jan. 31, 2013). The doctor's assessment was "rhinitis" and "acute viral pharyngitis." Id. at 79. This record, however, does not indicate that Ms. Cottingham was experiencing near black-outs or low-grade fevers. The doctor also did not memorialize that Ms. Cottingham has having headaches frequently after November 1, 2012. Ms. Cottingham's affidavit does not question the accuracy of this medical record. See exhibit 1 ¶ 9.

On March 29, 2013, Ms. Cottingham "fainted upon getting up this morning." Exhibit 3 at 80. She also had a "fever and dizziness," and "[v]omited once." Id. The doctor's assessment was "gastroenteritis" and "dehydration." Id. at 81. The doctor believed that Ms. Cottingham was "at the early stage of an intestinal virus." Id. at 80-81. March 29, 2013 is 267 days (nearly 9 months) after July 5, 2012, the date of the first HPV vaccination.

Ms. Cottingham fainted again on May 23, 2013, while at a pool. The history of present illness from her treatment after this incident states that after waking up that morning, Ms. Cottingham did not have anything to eat or drink. When at the pool with a friend, Ms. Cottingham felt "very hot" and "hungry" "so she stood up quickly to go get something to eat. She says at that point her vision became black and she felt very light headed. Soon after she fell backwards." Exhibit 3 at 70. The doctor thought that Ms. Cottingham "was dehydrated prior to this event. [She] also [thought] laying out in the sun may have contributed." Id. at 71. The doctor recommended that Ms. Cottingham increase her intake of fluids. Id.

On July 10, 2013, Ms. Cottingham had an appointment with her pediatrician (Dr. Simpson) for two reasons. The visit was, in part, for Ms. Cottingham's 15-year-old checkup. Ms. Cottingham's mother also raised a concern about the two

episodes of fainting and asked about an echocardiogram. Exhibit 3 at 96. Ms. Cottingham stated that she was having monthly menses. Id. Dr. Simpson confirmed that Ms. Cottingham should eat breakfast and should drink fluids throughout the day. Id. at 97. He also referred Ms. Cottingham to a cardiologist. Id. The only mention of vaccines in the note from July 10, 2013 is under "Counseling / Education," a statement that "Anticipatory guidance given and immunizations reviewed." Id.

On July 25, 2013, Ms. Cottingham visited the pediatric cardiology clinic of the University of Alabama-Birmingham. The history of present illness recounts the two incidents of fainting from March and May. In addition, it stated that Ms. Cottingham "has had other episodes of dizziness and near passing out. With all the episodes, she is standing or walking. She does not participate in any competitive athletics. She does participate as a majorette. She has not had any dizziness or syncope with physical activity." Exhibit 3 at 111. She further reported that "one time her episode improved when she sat down." Id. The doctor conducted various tests and determined that she had a "structurally and functionally normal heart. This syncope/presyncope is consistent with a vasovagal etiology." Id. at 112. The doctor "emphasized aggressive fluid hydration." Id. The cardiologist diagnosed Ms. Cottingham with vasovagal syncope. Id. The cardiologist did not refer her for autonomic testing.

Following the July 25, 2013 visit with the pediatric cardiologist, nearly eight months passed before the next medical record. On March 14, 2014, Ms. Cottingham went to the office of her pediatrician. Her chief complaint was listed as "cough, congestion, [sore throat], low-grade fever." Exhibit 3 at 106. The doctor's assessment was "cough," "acute viral pharyngitis," and "acute upper respiratory infection." Id.

Ms. Cottingham again saw a pediatrician for a checkup on August 18, 2014. The history of present illness states: "Been doing well. No concerns." Exhibit 3 at 109. The office notes also indicate that the date of Ms. Cottingham's last menstruation was July 25, 2014. They also say that an oral contraceptive was discontinued, although the date of discontinuance was not given. At this appointment, Ms. Cottingham received another dose of the hepatitis A vaccine, another dose of the meningococcal conjugate vaccine, and another dose of the HPV vaccine. Id. at 109-10.

Pursuant to a history given to a gynecologist in April 2015, Ms. Cottingham took oral contraceptives until October or November 2014 when her prescription ran out. This same history reports that Ms. Cottingham had a menstrual period in

December 2014, but none since that month. Exhibit 7 at 7.[3] The review of systems indicated that Ms. Cottingham reported "cold intolerance." Id. at 8. During the April 28, 2015 appointment, the gynecologist came to the impression that Ms. Cottingham was suffering from "secondary amenorrhea." Id. at 9. The doctor also indicated that polycystic ovarian syndrome was possible. The doctor ordered an ultrasound. Id.

Because of problems scheduling the ultrasound, Ms. Cottingham's mother called the office of Ms. Cottingham's pediatrician on May 14, 2015. Ms. Cottingham's mother was "concerned that the Gardasil series may have had something to do with the recent changes noted in [Ms. Cottingham's] menstrual cycle. Mom is requesting that a note be made in [her] chart regarding this concern." Exhibit 3 at 175.

The day after this May 2015 phone call, Ms. Cottingham's mother retained the petitioner's current attorney, Andrew Downing. Pet'r's Mot., filed Oct. 26, 2016, at 4. Within a few days, a paralegal was requesting information from Ms. Cottingham's mother to obtain medical records. Timesheets, pages 9-10.

Ms. Cottingham returned to the pediatric gynecology clinic of the University of Alabama-Birmingham on July 8, 2015. The doctor recorded that her abnormal uterine bleeding was now resolved with the use of oral contraceptives. The doctor continued the prescription. Exhibit 7 at 11-13.

B. Procedural History regarding Litigation's Entitlement Phase

At the law firm, a paralegal continued the process of requesting and obtaining medical records throughout the summer of 2015. On October 16, 2015, Mr. Downing reviewed the medical records received to date. Timesheets at 1. Shortly thereafter, Mr. Downing and his paralegal began working on a witness statement and drafting a petition. Timesheets at 1, 6.

Mr. Downing submitted the petition on October 30, 2015. He maintained in it that Ms. Cottingham first experienced symptoms of a condition the HPV vaccine caused on November 1, 2012. Therefore, in Mr. Downing's view, the 36-month statute of limitations expired on November 1, 2015. Pet'r's Mot. for Rev., filed Apr. 27, 2017, at 5.

[3] A duplicate of this record appears as exhibit 10, page 4.

The petition was not very specific. The introductory paragraph alleged that Ms. Cottingham suffered "a severe adverse reaction." Paragraph four of the petition references headaches that began on November 1, 2012. Paragraphs six and seven refer to episodes of fainting in March and May 2013, respectively. Paragraph eight recounts that Ms. Cottingham's mother was concerned about "autonomic dysfunction." Paragraph nine asserts that Ms. Cottingham began having menstrual problems in the latter part of 2013.

Over the next few months, Mr. Downing's office obtained more medical records and filed them. On March 15, 2016, Mr. Downing submitted a statement of completion, representing that Ms. Cottingham had filed all the medical records of which she was aware.

On March 28, 2016, a status conference was held. The Secretary stated that he was concerned about the reasonable basis for the petition. In response, Mr. Downing stated that Ms. Cottingham would attempt to retain an expert. See order, issued Mar. 28, 2016.

Mr. Downing called one doctor, whom Mr. Downing has retained in other Vaccine Program cases, Dr. Nemechek. However, Dr. Nemechek did not provide a favorable opinion. After consulting Ms. Cottingham's mother, Mr. Downing consulted a second expert, Dr. Lee. However, Dr. Lee also could not provide a favorable opinion. See Pet'r's Mot., filed Oct. 26, 2016, at 6-7.

On October 6, 2016, Ms. Cottingham filed a motion for a decision. Ms. Cottingham's case was dismissed due to a lack of evidence. See Decision Dismissing Case, 2016 WL 6575170.

C. Procedural History Relating to Petitioner's Motions for Attorneys' Fees and Costs

1. Initial Motion through Special Master's Initial Adjudications

Ms. Cottingham filed her first motion for attorneys' fees and costs on October 26, 2016. She devoted one section of her accompanying brief to an argument that reasonable basis supported her petition. Ms. Cottingham primarily contended that her attorney was required to file her petition before the expiration of the time set by the statute of limitations. Therefore, the standard for evaluating reasonable basis should be more lenient. Pet'r's Mot. for Attorneys' Fees and Costs, filed Oct. 26, 2016, at 7. While the thrust of Ms. Cottingham's argument in favor of a finding of reasonable basis was the looming statute of limitations, Ms. Cottingham also mentioned that she was diagnosed with syncope. Id. at 4 (citing

exhibit 3 at 111 (record dated July 25, 2013)). Ms. Cottingham continued: "Syncope is listed on the Gardasil product monograph as a known potential result of this vaccination, as well as a frequently reported side effect in the post-marketing experience." Id. Although Ms. Cottingham provided an internet link to the product monograph, she did not file it as an exhibit.

After this discussion about the requirements to be eligible for attorneys' fees and costs, Ms. Cottingham discussed the amount of attorneys' fees and costs that would be reasonable. Id. at 8-21. Ms. Cottingham concluded that a reasonable amount was $10,363.00 in attorneys' fees and $1,105.77 in costs. Ms. Cottingham supported her request with timesheets, invoices, and a memorandum approximately 10 pages in length. Ms. Cottingham's October 26, 2016 motion requested compensation for Mr. Downing's work through October 18, 2016, when the entitlement phase of Ms. Cottingham's case ended. In other words, the October 26, 2016 motion did not request any fees for preparing the fee application itself.

The Secretary argued that Ms. Cottingham's case lacked a reasonable basis. Resp't's Resp., filed Nov. 14, 2016. The Secretary's analysis was contained in two parts. First, the Secretary maintained "[t]he record contains no evidence to support a finding of reasonable basis." Id. at 4. The Secretary reviewed five pieces of evidence that Ms. Cottingham had cited in her motion. In this context, the Secretary filed a product monograph as exhibit A. See id. at 5 n.1. The Secretary maintained that the product monograph did not support a reasonable basis because "the relevant period of concern addressed in the document is '15 minutes after administration.'" Id. at 8 (citing exhibit A). In contrast, Ms. Cottingham's episodes of syncope occurred eight and ten months after vaccination and the doctors who treated her associated those syncopal episodes with dehydration.

The Secretary's second point against a finding of reasonable basis concerned the statute of limitations. To the Secretary, the pendency of the statute of limitations did not affect the analysis of reasonable basis. Id. at 11-13.

Ms. Cottingham submitted a reply, reinforcing and repeating her arguments regarding reasonable basis. Pet'r's Reply, filed Nov. 28, 2016. Ms. Cottingham added that an attorney's leaving a potential petitioner with only a short time either to find a new attorney to represent her or to file a case pro se would be tantamount to an ethical violation. Id. at 4 (citing Simmons v. Sec'y of Health & Human Servs., No. 13-825V, 2016 WL 59378528, at *3 (Fed. Cl. Spec. Mstr. Apr. 14, 2016)). Ms. Cottingham also replied to the Secretary's discussion of the evidence. Id. at 4-8. To Ms. Cottingham, the Secretary was "comingling the analyses for entitlement and reasonable basis." Id. at 4. Ms. Cottingham asserted that an article

by S. Blitshteyn supported a claim that the HPV vaccination can cause syncope "well outside of the 15-minute window." Id. at 7. However, Ms. Cottingham did not file this article.

Respondent submitted a sur-reply noting that the Court granted a motion for review in Simmons. Resp't's Notice of Add'l Auth., filed Nov. 28, 2016. The Court in Simmons stated: "[A] statute of limitations deadline does not excuse counsel from endeavoring to confirm that the vaccine injury alleged has occurred by producing supporting evidence." Simmons v. Sec'y of Health & Human Servs., 128 Fed. Cl. 579, 584 (2016).

The undersigned found that Ms. Cottingham did not satisfy the reasonable basis standard for two reasons. Cottingham v. Sec'y of Health & Human Servs., No. 15-1291V, 2017 WL 1476242 (Fed. Cl. Spec. Mstr. Mar. 30, 2017), vacated and remanded, 134 Fed. Cl. 567 (2017) [hereinafter "First Fees Decision"]. First, the undersigned interpreted the Vaccine Act as not allowing the reasonable basis standard to change because a statute of limitation was looming. Id. at *9-10. Second, the undersigned found that the evidence did not support a finding of reasonable basis. The First Fees Decision looked to see whether "medical records or medical opinions" supported the claims in the petition. Id. at *11. Because neither medical records nor medical opinions supported the assertion that the HPV vaccination caused Ms. Cottingham's headaches, fainting, or menstrual problems, the First Fees Decision did not award attorneys' fees and costs.[4] Id. at *6-11.

Ms. Cottingham sought reconsideration. Ms. Cottingham opened by arguing that an "evidence based standard" for evaluating reasonable basis "constitutes [an] error of law" and "violates the spirit and intent of the Vaccine Act[]." Pet'r's Mot. for Recons., filed April 7, 2017, at 1. Ms. Cottingham developed her argument that the statute of limitations should affect the reasonable basis analysis. Id. at 1-5. She also maintained that the undersigned "inappropriately applied an entitlement analysis." Id. at 5. Under this argument, Ms. Cottingham reviewed medical records, organized by whether her counsel received them before or after he filed the petition. A point of emphasis was that Ms. Cottingham submitted an affidavit about her headaches, which could have been credited despite its inconsistency with the medical records. Ms. Cottingham also maintained that when she started to experience symptoms was not part of the reasonable basis analysis because the

[4] The First Fees Decision also looked at the attorney's conduct. But, given later developments in Federal Circuit law, the attorney's conduct is no longer relevant in determining reasonable basis.

"appropriateness of onset under Althen prong 3 is a question for experts – not an attorney." Id. at 14. In this context, Ms. Cottingham quoted, but did not file, an article by Dr. Poser from 1982. Id.

The undersigned found that Ms. Cottingham's case did not warrant reconsideration. Cottingham v. Sec'y of Health & Human Servs., No. 15-1291V, 2017 WL 2209904 (Fed. Cl. Spec. Mstr. Apr. 20, 2017). The analysis was, again, split into two parts. The first issue was the continuing dispute over whether the pendency of the statute of limitations affects the analysis of reasonable basis. The second part was a review of the evidence. Although Ms. Cottingham had maintained that the First Fees Decision "cherry pick[ed] the evidence," she did not identify any records that were not discussed in the First Fees Decision. Id. at *3. Although Ms. Cottingham had maintained that her affidavit regarding the onset of her allegedly weekly headaches could have been credited, the lack of discussion in any medical record about "regular weekly headaches" made her affidavit "strain credibility." Id. at *4. Finally, Ms. Cottingham had not established that the First Fees Decision improperly considered the temporal relationship between the vaccination and the alleged onset of different conditions. Consequently, Ms. Cottingham's motion for reconsideration was denied.

2. First Motion for Review, First Opinion, and Second Fees Decision

Ms. Cottingham filed a motion for review. She argued that the looming statute of limitations and the conduct of an attorney for petitioners affected the analysis of reasonable basis. Pet'r's Mot. for Rev., filed April 27, 2017, at 2-6. Ms. Cottingham also argued that the special master erred by evaluating the case "under an elevated entitlement standard, not a reasonable basis standard." Id. at 8. Much of this aspect of the motion for review repeats arguments in the motion for reconsideration. Ms. Cottingham emphasized the value of her affidavit, particularly in regard to her allegation that she experienced headaches on a weekly basis. See, e.g., id. at 14. Ms. Cottingham argued that her attorney was not responsible for determining whether the onset of her various conditions fell within a medically appropriate time. Id. at 15-17. In this context, Ms. Cottingham again quoted a Poser article, which was not an exhibit. Id. at 17. Ms. Cottingham's April 27, 2017 motion for review did not reference the Blitshteyn article, which was not an exhibit, or the product monograph, which is exhibit A.

The Secretary responded to both themes. First, the Secretary argued that an evidence-based standard was appropriate for evaluating reasonable basis. Resp't's Resp., filed May 26, 2017, at 9-17. Second, the Secretary maintained that the

special master's finding that Ms. Cottingham did not satisfy the reasonable basis standard under the totality of circumstances test was not arbitrary or capricious. Id. at 17-20. As part of this argument, the Secretary contended that "[b]ecause the petition was alleging injuries [Ms. Cottingham] did not have and timeframes between vaccination and onset that were facially suspect and unsupported by any medical opinion or prior case decisions, a 'reasonable basis' for the petition's filing did not exist." Id. at 19.

Ms. Cottingham replied. She continued to press the value of her affidavit. Pet'r's Reply, filed June 2, 2017, at 2 (citing Vaccine Rule 2(c)(2)(B)). To Ms. Cottingham, the special master "baffl[ingly] . . . ignore[d] under-oath testimony." Id. Ms. Cottingham asserted that the undersigned "is the only Special Master to continue to espouse an evidence-based standard" for evaluating reasonable basis. Id. at 2. With respect to the evidence, Ms. Cottingham asserted that three articles connected the human papillomavirus vaccine to autonomic dysfunction. Id. at 9-10. However, the three articles (Martinez-Lavin, Kinoshita, and Brinth) were not filed as exhibits. Ms. Cottingham did not cite the product monograph, although she referred to the Vaccine Injury Table, which associates HPV vaccination with syncope that occurs within one hour. Id. at 10.

The Court granted the motion for review. Cottingham v. Sec'y of Health & Human Servs., 134 Fed. Cl. 567 (2017) [hereinafter "First Opinion"]. For each of the two reasons the First Fees Decision gave for finding that there was not a reasonable basis for the claim set forth in the petition, the Court stated that the standard was not correct. With respect to the discrepancy between Ms. Cottingham's affidavit and the contemporaneously created medical records, the Court stated: "To interpret these medical records to vitiate any reasonable basis for the claim places too onerous a burden on counsel at the pleading stage." Id. at 576. The Court continued: "Insisting that an injured claimant's testimony precisely mesh with medical records is too exacting a standard to apply in assessing whether a claim has a reasonable basis." Id.

The Court's ruling with respect to the temporal relationship between the vaccination and the onset of symptoms was similar. "The Special Master's conclusion that Petitioner's counsel was required to marshal evidence and precedent on the timing of onset of [HPV] vaccine injuries to establish a reasonable basis for filing a claim asks too much." Id. Accordingly, the Court vacated the First Fees Decision and remanded for additional adjudication under the standard articulated in its ruling.

After the Court issued its First Opinion, Ms. Cottingham filed a supplemental motion for attorneys' fees and costs. This motion captures efforts of Mr. Downing and others beginning October 21, 2016. The motion encompassed work on the October 26, 2016 motion for attorneys' fees and costs, the reply brief, the motion for reconsideration, and the motion for review. Ms. Cottingham sought $20,182.50 for attorneys' work in litigating the fee dispute as well as an additional $1,758.09 in costs. Pet'r's Supp'l Mot., filed Sept. 19, 2017. Following an informal request from the undersigned, Ms. Cottingham submitted her General Order #9 statement on November 6, 2017, indicating that Ms. Cottingham had not incurred any costs personally.

The undersigned found that under the Court's standard, Ms. Cottingham satisfied the reasonable basis standard. The undersigned did not consider the discrepancies between the medical records and Ms. Cottingham's affidavit. The undersigned also did not consider the latency between vaccination and the onset of Ms. Cottingham's headaches, fainting, or menstrual difficulties. Under the Court's standard, "[Ms. Cottingham's] affidavit, by itself, carries Ms. Cottingham's burden to establish a reasonable basis." Cottingham v. Sec'y of Health & Human Servs., No. 15-1291V, 2017 WL 6816709 (Fed. Cl. Spec. Mstr. Dec. 12, 2017), vacated and remanded, 139 Fed. Cl. 88 (2018) [hereinafter "Second Fees Decision"].

With respect to the amount of attorneys' fees and costs, the Second Fees Decision awarded Ms. Cottingham $32,909.36.

3. Second Motion for Review, Second Opinion, and Third Fees Decision

This time, the Secretary challenged the undersigned's decision. The Secretary argued that the Court should vacate its September 18, 2017 [First] Opinion and reinstate the First Fees Decision, issued on March 30, 2017. The basis for this argument was that in a precedential opinion, the Federal Circuit held that neither a looming statute of limitations nor the actions of counsel were part of the examination into reasonable basis. The Federal Circuit, instead, required an "objective inquiry." Resp't's Mot. for Rev., filed Jan. 10, 2018, at 9 (citing Simmons v. Sec'y of Health & Human Servs., 876 F.3d 632 (Fed. Cir. 2017)).

After discussing Simmons, the Secretary turned to the record in Ms. Cottingham's case. Referring the First Fees Decision, the Secretary maintained that "[b]ecause petitioner submitted no evidence to support the causation claim, the Special Master did not abuse his discretion in finding that the petitioner lacked a reasonable basis." Resp't's Mot. for Rev. at 14. In other words, "without any

evidence to support the causation claim, it is clear that petitioner fails to satisfy her burden for entitlement to compensation for attorneys' fees and costs under the reasonable-basis standard." Id. at 15 (emphasis in original). The Secretary further argued that "neither the affidavits nor [Ms. Cottingham's] medical records support a finding of reasonable basis." Id. (capitalization changed without notation). In doing so, the Secretary "respectfully object[ed]" to the Court's faulting the special master for expecting an affidavit to mesh with the medical records. Id. at 17.[5] Similarly, the Secretary also "respectfully object[ed]" to the First Opinion's determination that the special master wrongly required petitioner "to marshal evidence and precedent on timing of [Gardasil] vaccine injuries to establish a reasonable basis for filing a claim." Id. at 15.[6] Accordingly, the Secretary concluded that the Court should vacate its First Opinion and reinstate the First Fees Decision.

Ms. Cottingham argued that the Court should affirm the Second Fees Decision. Ms. Cottingham stated that Simmons was distinguishable from her case in that in Simmons, the petition was accompanied "by nothing – no medical records or affidavits." Pet'r's Resp. to Mot. for Rev., filed Feb. 5, 2018, at 5. In contrast, Ms. Cottingham "produced both sworn statements . . . as well as objective, medical evidence supporting [her] complaints." Id. at 6. "When [Ms. Cottingham's] affidavit is considered in context with her medical records, there is certainly evidence supporting the Petition's allegations. Furthermore, to say that Petitioner's filing in the Vaccine Program was not supported by any evidence is simply a mischaracterization of the facts." Id. at 8.

Ms. Cottingham also argued that in the Secretary's motion for review, the Secretary wrongly "comingles the causation and reasonable basis analysis." Id. at 9. The Secretary's approach, in Ms. Cottingham's view, was an attempt "to hold Petitioners to too high of a standard on reasonable basis." Id. at 10.

Finally, Ms. Cottingham addressed questions about temporal proximity. Citing the product monograph (exhibit A), she asserted that "the medical literature supports autonomic dysfunction as an adverse reaction that occurs well outside of

[5] The Secretary maintained this position, in part, to preserve the issue for potential Federal Circuit review. Id. at 12.

[6] Again, the Secretary noted that a Federal Circuit appeal on this issue was possible. Id. at 15.

the 15-minute window." Id. at 10. Ms. Cottingham again cited, but did not file, articles by Blitshteyn, Martinez-Lavin, Kinoshita, and Brinth. Id. at 10-11.

The Court granted the motion for review and vacated the Second Fees Decision. The Court ruled in an opinion issued on May 31, 2018, that the undersigned misinterpreted the Court's First Opinion in that "the Court did not find that [Ms. Cottingham's] affidavit alone would suffice to establish a finding of reasonable basis. Rather, this Court held that the medical records could be reconciled with the relevant testimony, and the two were not necessarily inconsistent." Cottingham v. Sec'y of Health & Human Servs., 139 Fed. Cl. 88, 94 (2018). Accordingly, the Court remanded with these instructions and to consider the effect of Simmons.

After reviewing the evidence again, the undersigned found that Ms. Cottingham did not satisfy the reasonable basis standard. Based upon Simmons, the Third Fees Decision looked for evidence relating to claims set forth in the petition. The Third Fees Decision defined the claims set forth in the petition as "the HPV vaccination caused headaches within about four months, the HPV vaccination caused fainting roughly nine months later, and the HPV vaccination caused menstrual difficulties starting approximately 18 months later." Cottingham v. Sec'y of Health & Human Servs., No. 15-1291V, 2018 WL 3432638, at *5 (Fed. Cl. Spec. Mstr. June 20, 2018), mot. for rev. denied, 141 Fed. Cl. 85 (2018), vacated and remanded, 971 F.3d 1337 (Fed. Cir. 2020) [hereinafter "Third Fees Decision"]. To the undersigned, the key topic was "causation." Accordingly, the undersigned looked for either a medical record or a medical opinion in which a medical doctor associated a vaccination with a medical problem. The undersigned found neither a medical opinion from a retained expert nor a medical record from a treating doctor. Accordingly, the undersigned found that Ms. Cottingham did not meet the reasonable basis standard. The undersigned did not discuss the product monograph, which had been filed as exhibit A. The undersigned also did not discuss the articles to which Ms. Cottingham had referred but had not filed.

4. Third Motion for Review and Third Opinion

Ms. Cottingham filed her second motion for review on July 19, 2018, in which she requested the Court reverse the June 20, 2018 Fees Decision and award the petitioner $32,909.36 in attorneys' fees. Pet'r's 2d Mot. for Rev., filed July 19, 2018, at 2. Ms. Cottingham developed her arguments in a memorandum filed in conjunction with the motion.

To Ms. Cottingham, the Court's *First* Opinion should have dictated the result. According to Ms. Cottingham, the Court did the following:

> 1) construed the nature of the medical claims made; 2) documented that the symptoms and nature of the medical claims being made were reflected in the medical chart; 3) found that the medical chart corroborated the under-oath testimony from Petitioner, and 4) timing was acceptable – especially given that the onset timing for Gardasil injuries is not established.

Pet'r's Mem. Supporting Pet'r's 2d Mot. for Rev. at 7. Ms. Cottingham argued that the undersigned ignored these instructions and wrongly expanded the analysis of reasonable basis "into a causation analysis." Id. Ms. Cottingham maintained that she "provided medical records that substantiate her claims of vaccine injury causing harm." Id. at 8. (However, Ms. Cottingham did not cite any medical records in this portion of her brief.) Ms. Cottingham also challenged the proposition that supplying a medical opinion or medical record was the standard for evaluating reasonable basis. Id. In addition, Ms. Cottingham argued that the special master "failed to consider the novelty of the Gardasil vaccination and the ever-increasing body of medical literature supporting insidious onset of Gardasil injuries." Id. at 6.

In contrast, the Secretary defended the June 20, 2018 decision. According to the Secretary, the "Special Master correctly observed that in this case, petitioner had not submitted any evidence to support her claim that [an] HPV vaccine caused [her] to suffer headaches, fainting, and/or menstrual problems." Resp't's Resp. to Pet'r's 2d Mot. for Rev., filed Aug. 20, 2018, at 2. The Secretary elaborated: "Because petitioner submitted no evidence to support causation, the Special Master necessarily concluded that petitioner failed to establish a reasonable basis for the claim for which the petition was brought under the objective inquiry for reasonable basis endorsed by Simmons." Id. at 2-3 (emphasis in original).

The Secretary disputed Ms. Cottingham's argument that the undersigned disregarded the Court's previous guidance. To the Secretary, the undersigned "weighed the affidavit evidence favorably, as previously directed." Id. at 5-6. But, to the Secretary, Ms. Cottingham had not produced any evidence that the HPV vaccination caused any problem in her. "In any off-Table case, petitioner must do more than establish that the alleged injuries occurred; petitioner's burden is to prove that the alleged injuries occurred and the vaccine was their cause." Id. at 7 (emphasis in original).

The Secretary further argued that "there is no objective evidence that [Ms. Cottingham] suffered chronic headaches beginning four months after her HPV vaccine." Id. at 11. Similarly, the Secretary maintained that the onset of fainting (8 and 10 months after vaccination) and menstrual difficulties (18 months after vaccination) "appear too remote in time from her HPV vaccine to be considered temporally proximate." Id. at 12. For both points, the Secretary advised that he wanted to preserve any objection for a possible appeal to the Federal Circuit.

In reply, Ms. Cottingham argued requiring "evidence of vaccine causation to find reasonable basis . . . is simply not the law." Pet'r's Reply, filed Aug. 27, 2018, at 2. Consistent with this view of the law, Ms. Cottingham stated the "fact that her medical chart does not say 'HPV vaccination is the cause' is not a requirement of a reasonable basis test." Id. at 4. Instead, Ms. Cottingham maintained that "[t]here is objective evidence in this record regarding symptoms present and their correlation back to vaccination." Id. at 3. However, Ms. Cottingham did not cite any evidence in this passage. After making additional arguments, Ms. Cottingham concluded by requesting that the Court reverse the Third Fees Decision and award her $32,909.36 in attorneys' fees and costs, or, alternatively, remand for further proceedings for an award of reasonable attorneys' fees and costs. Id. at 7.

The Court denied the motion for review. The Court ruled that the special master did not impose too high a burden of proof to establish reasonable basis. In the Court's view, the special master did not require Ms. Cottingham "to satisfy the Althen factors or otherwise demonstrate causation in fact." Cottingham v. Sec'y of Health & Human Servs., 141 Fed. Cl. 85, 88 (2018), vacated and remanded, 971 F.3d 1337 (Fed. Cir. 2020) [hereinafter "Third Opinion"]. "Rather, in concluding that Petitioner's claim lacked a reasonable basis, the Special Master focused on the lack of evidence in Petitioner's medical records and the treating physicians' diagnosis, along with the absence of any expert opinion or supporting literature." Id. at 88-89.

In addition, the Court disagreed with Ms. Cottingham's argument that the special master disagreed with an earlier finding from the Court. "Contrary to Petitioner's argument, this Court did not reassess the sufficiency of Petitioner's offered evidence or find that Petitioner had in fact provided sufficient evidence to demonstrate that her claim had a reasonable basis." Id. at 88. Thus, on December 28, 2018, a judgment denying her attorneys' fees and costs was entered.

5. Federal Circuit

Ms. Cottingham appealed the judgment to the Federal Circuit. Ms. Cottingham argued that to establish reasonable basis, petitioners must present evidence that is "'markedly less than needed to prove causation.'" Br. of Pet'r-Appellant, filed May 14, 2019, at 16 (quoting Bekiaris v. Sec'y of Health & Human Servs., 140 Fed. Cl. 108, 114 (2018)). Ms. Cottingham further argued that she met this standard because "she provided evidence demonstrating her receipt of a covered vaccination. Petitioner presented evidence in her medical chart documenting the very injuries and symptoms which she claimed was related to her receipt of said vaccination. Petitioner articulated a rational and reasonable causal connection between the two. Reasonable basis exists." Id.

Ms. Cottingham directed the Federal Circuit to earlier briefs (discussed above) in which she cited medical articles by Blitshteyn, Martinez-Lavin, Kinoshita, and Ozawa. Id. at 17-18. Ms. Cottingham also asserted that the HPV vaccination was a novel vaccination. Ms. Cottingham next reviewed the material contained in medical records and maintained that medical records support the assertions in her affidavit. See id. at 20-25. In this context, Ms. Cottingham stated that the product monograph for Gardasil "connect[s]" the HPV vaccine with "headache, nausea, syncope, abdominal pain and dizziness." Id. at 23. In conclusion, based upon those arguments, Ms. Cottingham requested that the Federal Circuit vacate the decision and "remand with instructions to award attorneys' fees and costs." Id. at 27.

In response, the Secretary urged the Federal Circuit to confirm that Simmons, in his view, had rejected the "totality of the circumstances test." Br. of Resp't-Appellee, filed June 5, 2019, at 12-17. In terms of Ms. Cottingham's case, the Secretary maintained the decision that the petition lacked a reasonable basis should be affirmed because she "submitted no evidence on a critical element – specifically, vaccine-causation." Id. at 17. To the Secretary, although Ms. Cottingham "discusses certain medical records that allegedly 'support [her] injury claim,' those records merely document that [she] was experiencing certain symptoms in the several months after her vaccination; they do not causally relate those symptoms to the Gardasil vaccine." Id. at 19 (quoting Br. of Pet'r-Appellant at 9).

The Secretary reviewed various pieces of evidence on which Ms. Cottingham relied. The Secretary maintained that the alleged onset of headaches (approximately four months after the vaccination) presented an immediate and obvious "obstacle to proving causation." Id. at 21. The Secretary disputed Ms.

Cottingham's characterization of the HPV vaccination as "novel." Id. The Secretary noted that the articles on which Ms. Cottingham was relying were not part of the record and that the articles, by their titles, addressed different conditions. Id. at 22-23. The Secretary, however, did not address the product monograph, which the Secretary had filed into the record as exhibit A.

The Federal Circuit granted Ms. Cottingham some, but not all, of the relief she sought. The Federal Circuit vacated the December 28, 2018 judgment. However, as discussed below, the Federal Circuit did not order an award of attorneys' fees, remanding that question.

As to the question regarding whether special masters may consider "the totality of the circumstances," the Federal Circuit stated that Simmons did not reject this test. Cottingham v. Sec'y of Health & Human Servs., 971 F.3d 1337, 1344-45 (Fed. Cir. 2020). Petitioners can satisfy the "objective test" of reasonable "through objective evidence." Id. at 1344.

The Federal Circuit further explained that petitioners "must point to evidence of a causal relationship between the administration of the vaccine and [their] injuries in order to establish that a reasonable basis for the claim existed when the petition was filed." Id. at 1346. This evidence is lower than the preponderance of evidence standard. "Indeed, more than a mere scintilla but less than a preponderance of evidence could provide sufficient grounds for a special master to find reasonable basis." Id.

When the Federal Circuit measured the information that Ms. Cottingham had provided, the Federal Circuit deemed the undersigned's statement that Ms. Cottingham had "presented 'no evidence' that supported [her] assertion that the Gardasil vaccination caused [her] injuries" constituted reversible error in that it "rests on a clearly erroneous fact finding." Id. at 1344-45.

6. Remand After Federal Circuit Opinion, Fourth Decision, and the Federal Circuit's Opinion in *James-Cornelius*

After the Federal Circuit issued its mandate and an order was issued remanding the case back to the undersigned on October 14, 2020, the undersigned issued an order setting out a briefing schedule on October 15, 2020. The parties filed initial briefs on November 19, 2020, and filed reply briefs on December 7, 2020. The undersigned then scheduled an oral argument for December 14, 2020, and issued some guidance on the content of the oral argument on December 11, 2020. Oral argument was held remotely via videoconferencing on December 14,

2020. Oral argument proved helpful in extrapolating the parties' various points on remand.

The undersigned issued a decision on January 7, 2021, again denying Ms. Cottingham's motion for attorneys' fees and costs. Cottingham v. Sec'y of Health & Human Servs., No. 15-1291V, 2021 WL 347020 (Fed. Cl. Spec. Mstr. Jan. 7, 2021), vacated and remanded, No. 15-1291V, 2021 WL 3085502 (Fed. Cl. July 21, 2021[hereinafter "Fourth Fees Decision"]. In this decision, the undersigned re-assessed certain pieces of evidence highlighted by the Federal Circuit, including: (1) certain medical records, (2) affidavit testimony, and (3) the package insert. Id. at *19-27. The undersigned also considered additional medical articles filed by Ms. Cottingham. Id. at *27-31. The undersigned found that, while Ms. Cottingham had supplied some evidence regarding reasonable basis, under the totality of the circumstances, she had not met her burden to show that her claim was properly supported by a reasonable basis.

The next day, the Federal Circuit issued its opinion in James-Cornelius v. Secretary of Health & Human Services, 984 F.3d 1374 (Fed. Cir. 2021). In this decision, the Federal Circuit re-examined the reasonable basis standard, specifically focusing on evaluation of affidavits and testimony as evidence of reasonable basis, as well as the necessity (or lack thereof) of an expert medical opinion to establish reasonable basis. Most notably, the Federal Circuit emphasized that medical records, affidavits, and sworn testimony all constitute objective evidence. James-Cornelius, 984 F.3d at 1379-81. Therefore, special masters must consider these forms of evidence in evaluating reasonable basis. Additionally, the Federal Circuit stated that "absence of an express medical opinion on causation is not necessarily dispositive of whether a claim has reasonable basis." Id. at 1379 (citing Cottingham, 971 F.3d at 1346). Thus, as the Court ruled, medical records without support from an expert opinion can satisfy the reasonable basis standard because "the lack of an express medical opinion on causation d[oes] not by itself negate the claim's reasonable basis." Id. at 1380.

The undersigned has incorporated the dictates of the James-Cornelius opinion into his analysis on this remand. In doing so, the undersigned has considered and weighed all objective evidence of reasonable basis, including affidavit evidence. The undersigned has also considered the medical records and literature separate from the lack of express medical opinion in this case. That is, the undersigned does not treat the absence of a medical opinion in this case as dispositive of the issue of reasonable basis.

7. Fourth Motion for Review

On February 5, 2021, Ms. Cottingham filed a motion for review. She argued first that the Federal Circuit's decision in James-Cornelius, issued one day after the undersigned issued the fourth Cottingham decision on remand, further clarified the reasonable basis standard and that the combination of medical records, product insert, and affidavit testimony present in her case provided objective evidence of causation, as in James-Cornelius. Pet'r's Mot. for Rev., filed Feb. 5, 2021, at 4-8. Second, Ms. Cottingham argued that the undersigned's weighing of certain pieces of evidence amounted to a violation of the standards set out by the Federal Circuit in Cottingham and James-Cornelius by elevating the burden associated with the reasonable basis standard. Id. at 8-19.

In response, the Secretary argued first that the undersigned thoroughly considered and discussed the pieces of evidence highlighted by the Federal Circuit, as well as additional medical articles, and rationally made a determination based on the totality of the circumstances. Resp't's Resp., filed Mar. 8, 2021, at 8-14. Second, the Secretary argued that, in considering all evidence, including affidavit testimony—and not relying solely on the absence of a medical opinion in the ultimate determination—the undersigned weighed the evidence in accordance with Cottingham and James-Cornelius. Id. at 14-20.

Ms. Cottingham filed a reply on March 15, 2021. In this reply, Ms. Cottingham homed in specifically on what she characterizes as an over-emphasis and erroneous reliance on the lack of opinions of treating physicians or expert witnesses in the reasonable basis analysis. Pet'r's Reply, filed Mar. 15, 2021, at 2-4. She also argues against the "undermining" of the weight of the package insert as objective evidence of reasonable basis. Id. at 4-5. Ms. Cottingham emphasized the relevance of the affidavit testimony, as well as certain medical articles filed. Id. at 5-7. Finally, she argues against what she deems a "conflation" of the reasonable basis and entitlement standards by the Secretary in his response and the undersigned in his decision. Id. at 7.

The Court granted the motion for review and vacated the Fourth Fees Decision. The Court ruled in an opinion issued on July 21, 2021, that the undersigned "erred in requiring Petitioner to adduce medical opinions from treating physicians or experts to establish reasonable basis." Cottingham v. Sec'y of Health & Human Servs., No. 15-1291V, 2021 WL 3085502 (Fed. Cl. July 21, 2021) [hereinafter "Fourth Opinion"]. The Court remanded the case "for a reassessment of reasonable basis without requiring a medical or expert opinion

supporting causation." The Court provided the following instructions as assessments for the undersigned to undertake on remand:

1) shall evaluate the totality of the circumstances, including:
    a. The import of James-Cornelius;
    b. The import of the Gardasil package insert, considering 21 C.F.R. § 201.57;
    c. The policies of the Vaccine Act encouraging petitioners to file and obtain qualified counsel to assist them; and
2) need not focus exclusively on the Althen factors but may consider other pertinent factors such as the novelty of the vaccine and the claimed injuries.

Fourth Opinion, 2021 WL 3085502, at *8. After the Court of Federal Claims issued its order remanding the case back to the undersigned on July 6, 2021, the undersigned held a status conference with the parties and issued an order setting out a briefing schedule on July 8, 2021.

8. Summary of the Arguments after Fourth Remand

After the remand order was issued, the parties filed simultaneous briefs on August 9, 2021, and Ms. Cottingham filed a reply brief on August 23, 2021.

Ms. Cottingham structured her brief by addressing each of the areas of consideration outlined by the Court of Federal Claims in turn: (1) the effect of the Federal Circuit's opinion in James-Cornelius; (2) regulations pertaining to package inserts; (3) policy considerations; and (4) novelty. First, Ms. Cottingham emphasized the two major points from the James-Cornelius opinion: that affidavits constitute objective evidence of reasonable basis, and that a lack of a medical opinion is not dispositive in determining whether a reasonable basis exists. Ms. Cottingham argues that she has provided an under-oath affidavit as well as medical records that provide objective evidence of reasonable basis and need not be corroborated or supported by an expert opinion according to the standard set out in James-Cornelius. See Pet'r's Br., filed Aug. 9, 2021, at 4. Ms. Cottingham quoted the Federal Circuit's opinion in stating: the "absence of an express medical opinion on causation is not necessarily dispositive of whether a claim has a reasonable basis, especially when the case is in its early stages and counsel may not have had the opportunity to retain qualified experts." Id. at 2 (quoting James-Cornelius, 984 F.3d at 1379). Ms. Cottingham pointed out that the vaccinee in James-Cornelius complained about injuries, headache and syncope, that are "the exact same injuries at issue here." Id. Ms. Cottingham noted that James-Cornelius "clarified the

standard that affidavits are objective evidence in the reasonable basis analysis." Id. at 4. Finally, Ms. Cottingham commented that the special master on remand in James-Cornelius awarded attorneys' fees and costs.

Second, with respect to consideration of package inserts, Ms. Cottingham cites 21 C.F.R. § 201.57(c)(7) in emphasizing that "adverse events" as defined for the purposes of product inserts include "only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." Id. at 5 (quoting 21 C.F.R. § 201.57(c)(7)). Ms. Cottingham thus argues that, based on this definition, any adverse events indicated by product inserts that match symptoms contained in Ms. Cottingham's medical records at least meet the relatively lower standard to establish reasonable basis. Id. at 5-6 ("As the Federal Circuit clearly stated, symptoms contained in the Petitioner's medical chart that are also listed in the product monograph is important evidence of reasonable basis."). Ms. Cottingham also contended that any examination of the product insert was not appropriate in determining whether reasonable basis supports her claims. Questions about the "time frames measured during the clinical trials" and whether the petitioner's symptoms "are exactly like what others experienced" could be addressed only during an entitlement hearing, not in a reasonable basis inquiry. Id. at 15. Ms. Cottingham summed up her comments about the package insert by quoting the Federal Circuit's opinion in this case: "K.C.'s medical records paired with the Gardasil package insert thus constitute at minimum circumstantial, objective evidence supporting causation." Id. at 6, quoting Cottingham v. Sec'y of Health & Human Servs., 917 F.3d 1337, 1346 (Fed. Cir. 2020).

Third, with respect to policy considerations, Ms. Cottingham argues that the attorneys' fees and costs structure in place is set up to ensure petitioners' access to competent counsel and cites multiple cases to support this point. Id. at 6-7 (quoting Avera v. Sec'y of Health & Human Servs., 515 F.3d 1343, 1352 (Fed. Cir. 2008); Saunders v. Sec'y of Health & Human Servs., 25 F.3d 1031, 1035 (Fed. Cir. 1994); McKellar v. Sec'y of Health & Human Servs., 101 Fed. Cl. 297, 302 (2011); Sheppard v. Sec'y of Health & Human Servs., No. 19-632V, 2021 WL 2210664, at *4 (Fed. Cl. Spec. Mstr. May 3, 2021)). Ms. Cottingham also states that a finding against reasonable basis in this case will contribute to a "chilling effect on an injured person's access to Counsel." Id. at 8.

Finally, regarding the role of novelty in this case, Ms. Cottingham states that the HPV vaccine is the most novel of the vaccines dealt with in the Program and that "there has been an explosion of medical literature over the past few years regarding the adverse effects of the HPV vaccination." Id. She points to exhibits

11-15 in this case as emerging research findings that provide evidence of her claim and further contribute to reasonable basis. Id. at 8-11.[7]

In his brief filed simultaneously with Ms. Cottingham's, the Secretary focuses mainly on policy considerations and the effect of James-Cornelius in according special masters wide discretion in weighing evidence to determine the issue of reasonable basis. The Secretary defers to the undersigned's previous findings regarding the effect of the package inserts. See Resp't's Br., filed Aug. 9, 2021, at 7 n.3. He also briefly addresses novelty by stating that, unlike claims that are routinely found to be meritorious, novel claims like the one in this case could require some specific evidence of causation to establish reasonable basis. Id. at 7 n.4.

Regarding policy considerations, the Secretary acknowledges that awards of attorneys' fees and costs are made potentially available in uncompensated cases to encourage petitioners' access to competent counsel. However, the Secretary emphasizes that requiring a reasonable basis for uncompensated claims serves another policy goal: "encouraging petitioners and their counsel to exercise appropriate diligence and judgment, and only bring claims that have some basis in science, fact, and law." Id. at 3. Furthermore, the Secretary cites to the number of attorneys listed on the Court of Federal Claims website as practicing vaccine injury law, as well as the increasing number of petitions filed in the Program, as evidence that the limitation of the reasonable basis standard is not having a practical effect on petitioners' access to counsel practicing in the Vaccine Program. Id. at 4. The Secretary also argues that because reasonable basis should be determined based on "objective evidence," policy considerations should ultimately have no bearing on the reasonable basis determination in this case because they are inherently subjective in nature. Id. at 6.

Finally, the Secretary characterizes the effect of James-Cornelius as defining what constitutes objective evidence of reasonable basis, while allowing for wide discretion with respect to the special master's weighing of this evidence to make an ultimate determination. The Secretary further argues that the undersigned has acted within his discretion in previously articulating multiple rational reasons for a

[7] As discussed in more detail in section V.C., the evidence supporting the "explosion" of literature consists of (1) an article published in 2014 regarding postural orthostatic tachycardia syndrome, (2) an article by Japanese researchers also published in 2014, (3) another article about postural orthostatic tachycardia syndrome published in 2015, (4) an article about small fiber neuropathy published in 2015, and (5) a second article by the Japanese researchers published in 2017.

denial of fees based on a lack of reasonable basis, and cites a Supreme Court case that states that appellate courts "must give substantial deference" to determinations regarding fee-shifting. Id. at 8-9 (quoting Fox v. Vice, 563 U.S. 826, 838 (2011)).

In her reply brief, Ms. Cottingham responds to the Secretary's alternate policy arguments, as well as the application of the standards articulated in James-Cornelius to this case. First, Ms. Cottingham argues that the standard the Secretary would impose to serve the policy goal articulated in his brief is "overly burdensome" and distinguishes the Secretary's partial reliance on Simmons by emphasizing the total lack of objective evidence in that case. See Pet'r's Reply, filed Aug. 23, 2021, at 1-2. Ms. Cottingham also takes issue with the Secretary's characterization that there is a large number of petitioners' attorneys practicing in the Vaccine Program, citing data and arguing that the argument that "Vaccine Act work is a flourishing area of legal practice" is "baseless." Id. at 3-4.

Finally, in responding to the Secretary's application of James-Cornelius, Ms. Cottingham ultimately reiterates that she has provided sufficient objective evidence to support a finding of reasonable basis in the form of "under-oath testimony, medical records, vaccination product information, and medical literature connecting the injury back to the vaccination given." Id. at 2. Furthermore, the novelty of the claim, Ms. Cottingham argues, should only add to the evidence of reasonable basis. Id.

II. Scope of Remand

The January 7, 2021 decision described the parties' conflicting interpretations about the degree, if any, of discretion for the undersigned to determine reasonable basis. Ultimately, the undersigned held that the Federal Circuit's opinion did not dictate a result.

> Preliminarily, the parties dispute the scope of the Federal Circuit's remand. To Ms. Cottingham, a denial of attorneys' fees would constitute "legal error." Pet'r's Br., filed Nov. 19, 2020, at 4. Ms. Cottingham bases this argument on Federal Circuit statements such as "the record does contain objective evidence of causation supporting a reasonable basis," and "[Ms. Cottingham's] medical records paired with the Gardasil package insert thus constitute at minimal circumstantial, objective evidence supporting causation." Id. at 3-4 (quoting Cottingham v. Sec'y of Health & Human Servs., 917 F.3d 1337, 1346 (Fed. Cir. 2020)); accord id. at 17.

On the other hand, the Secretary maintains the "Special Master absolutely possesses discretion on remand to find that petitioner has not satisfied the reasonable basis standard." Resp't's Br., filed Nov. 19, 2020, at 1. To the Secretary, the key passage from the Federal Circuit is the statement: "To be clear, we make no determination on the weight of the objective evidence in the record or whether that evidence establishes reasonable basis, for these are factual findings for the Special Master, and not this court." Id. (quoting Cottingham, 917 F.3d at 1346-47).

As a subordinate tribunal, the undersigned must abide by the mandate of a reviewing appellate authority. The undersigned interprets the Federal Circuit's opinion as not dictating a result on remand.

In other cases, the Federal Circuit has defined its scope of review. Ordinarily, the Federal Circuit does not find facts. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d 1363, 1366 (Fed. Cir. 2013); Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 868-71 (Fed. Cir. 1992). But see Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009) (finding that petitioners were entitled to compensation).

"Upon return of its mandate, the district court cannot give relief beyond the scope of that mandate, but it may act on matters left open by the mandate." Laitram Corp. v. NEC Corp., 115 F.3d 947, 951 (Fed. Cir. 1997) (quoting Caldwell v. Puget Sound Elec. Apprenticeship & Training Tr., 824 F.2d 765, 767 (9th Cir. 1987)) (internal quotation marks omitted). Here, as the Secretary points out, see Resp't's Br. at 1, the Federal Circuit did not reverse the outcome. Instead, the Federal Circuit vacated and remanded.

Accordingly, the undersigned interprets the Federal Circuit's opinion and mandate as requiring a re-examination of the evidence under the totality of circumstances to determine whether Ms. Cottingham possessed a reasonable basis for the claim set forth in the petition. The undersigned understands the Federal Circuit did not require a particular result.

Fourth Fees Decision, 2021 WL 347020, at *12-13.

After this fourth decision, the Court of Federal Claims again remanded the case and this remand also raises questions about latitude on remand because a statement from the Court of Federal Claims is binding on the assigned special master on remand. Hanlon v. Sec'y of Health & Human Servs., 40 Fed. Cl. 625, 630 (1998) ("Special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand.").

In its Fourth Opinion, it appears that the Court of Federal Claims also did not state the outcome to the reasonable basis inquiry. The Court stated: "On remand, the Special Master shall determine whether Petitioner established a reasonable basis for her claim." Fourth Opinion, 2021 WL 3085502, at *8. For their part, the parties do not argue that the Court's July 6, 2021 Opinion requires a result.

III. Standards for Adjudication

When a petitioner does not receive compensation (like Ms. Cottingham here), a petitioner remains eligible for an award of attorneys' fees and costs when a special master "determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought." 42 U.S.C. § 300aa–15(e). Here, the Secretary has not raised a challenge to Ms. Cottingham's good faith. Thus, the disputed issue is reasonable basis.

The precise standard by which special masters should evaluate claims of reasonable basis is still being fleshed out. However, some points about reasonable basis have been established in the last few years. The evidentiary standard for determining reasonable basis is less than the preponderance of the evidence. Chuisano v. Sec'y of Health & Human Servs., No. 07-452V, 2013 WL 6324660, at *12-13 (Fed. Cl. Spec. Mstr. Oct. 25, 2013), mot. for rev. denied, 116 Fed. Cl. 276 (2014).

When a petitioner submits literally no evidence, then a petitioner lacks a reasonable basis. Simmons v. Sec'y of Health & Human Servs., 875 F.3d 632 (Fed. Cir. 2017). Simmons, thus, clarified that petitioners meet their burden to establish reasonable basis by presenting objective evidence. Id. at 635-36.[8]

[8] As outlined in the procedural history, much of the parties' arguments in earlier portions of the case concerned whether Ms. Cottingham's affidavit constituted evidence supporting

In cases in which petitioners submit some objective evidence, Simmons does not control the result. The Federal Circuit saw the present case as one in which Ms. Cottingham had presented some evidence of reasonable basis. Thus, the Federal Circuit reasoned "more than a mere scintilla but less than a preponderance of proof could provide sufficient grounds for a special master to find reasonable basis." Cottingham, 917 F.3d at 1346.

The operative word in that quotation is "could." The presence of "more than a mere scintilla" of evidence does not mandate a finding of reasonable basis. This lesson is demonstrated by the Federal Circuit's earlier precedential opinion on reasonable basis, Perreira v. Secretary of Health & Human Services. In that case, the Perreiras alleged that a 1982 administration of the diphtheria-pertussis-tetanus ("DPT") vaccine harmed their daughter, Carly. Initially, the Perreiras maintained that Carly started having seizures four days after the second dose of DPT, based upon the testimony of Carly's mother. The former Chief Special Master declined to credit Ms. Perreira's testimony and found, instead, that the seizures started 20 days after the second dose of DPT. Perreira v. Sec'y of Health & Human Servs., No. 90-847V, 1991 WL 117740, at *1, 1 n.2 (Cl. Ct. Spec. Mstr. June 13, 1991).

Given this fact finding regarding the sequence of events, the Perreiras attempted to establish a significant aggravation claim. They based this alternative claim on the contention that two weeks after the third dose of DPT, Carly had more seizures. The Chief Special Master rejected the Perreiras' claim because there was no support for their expert's opinion that DPT causes harm that would first appear two weeks later. Id.

After the entitlement proceedings concluded, the Perreiras sought an award for their attorneys' fees and costs. The Chief Special Master found that the Perreiras had a reasonable basis for filing their petition. Perreira v. Sec'y of Health & Human Servs., No. 90-487V, 1992 WL 164436, at *2 (Cl. Ct. Spec. Mstr. June 12, 1993).

The decision does not provide a reason for finding reasonable basis. However, the Chief Special Master explicitly found that a reasonable basis no longer existed after the expert submitted a report, noting that the expert's theory

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reasonable basis. But, after the Federal Circuit opinion in Cottingham, the Federal Circuit held that a petitioner's affidavit regarding his or her symptoms is one form of "objective evidence" a special master must consider in determining reasonable basis. James-Cornelius, 984 F.3d at 1379-81.

"amounted to his own unsupported speculation[,]" and that the Perreiras' attorney should have recognized that the expert's theory "was legally insufficient to establish causation." Id. at *1-2. The Chief Special Master also stated that the Perreiras' attorney recognized that this case "was a 'bad case.'" Id.

The Perreiras filed a motion for review of the denial of a portion of the attorneys' fees and costs. In finding the former Chief Special Master's determination not arbitrary, the Court of Federal Claims rejected the petitioners' arguments, including an argument that "counsel had an absolute right to rely on the expert's opinion in pursuing the case." Perreira v. Sec'y of Health & Human Servs., 27 Fed. Cl. 29, 33 (1992).

These decisions form the background for the Federal Circuit's discussion of "reasonable basis" in its Perreira opinion. Affirming the original decision, the Federal Circuit held that the Chief Special Master could determine that a petitioner lacked reasonable basis, despite an expert report, because "the expert opinion was grounded in neither medical literature nor studies." Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 (Fed. Cir. 1994). The Federal Circuit explained that "[t]he special master did not require counsel to verify the validity of the expert's opinion, but only required the opinion to be more than unsupported speculation." Id.

"Perreira demonstrates that special masters enjoy discretion to find that a claim lacked a reasonable basis when the evidence on which the petitioners relies (there, an expert's report) is rooted in unsupported speculation." Ellis v. Sec'y of Health & Human Servs., No. 13-336V, 2019 WL 3315326, at *4 (Fed. Cl. Spec. Mstr. June 24, 2019). The Federal Circuit guided the "reasonable basis" standard by declaring: "Congress must not have intended that every claimant, whether being compensated or not under the Vaccine Act, collect attorneys' fees and costs by merely having an expert state an unsupported opinion." 33 F.3d at 1377.

It appears that the testimony of an expert constitutes "more than a mere scintilla" of evidence. If so, then Perreira demonstrates that a petitioner could present some evidence regarding causation and yet not satisfy the reasonable basis standard.

While the Federal Circuit did not cite Perreira in Cottingham or James-Cornelius, the Federal Circuit's use of the term "could" in Cottingham also suggests that special masters can reach different outcomes and those disparate outcomes might all be rational. In the context of determining whether petitioners

have met their burden to present preponderant evidence supporting causation, appellate authorities have recognized that questions of causation turn on the evidence presented, and reasonable special masters may weigh evidence differently. Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1368 (Fed. Cir. 2000); Estep v. Sec'y of Health & Human Servs., 28 Fed. Cl. 664, 669 (1993). Different outcomes among special masters as to the weight and "utility" of scientific and factual evidence are "within Program standards." Sharpnack v. Sec'y of Health & Human Servs., 27 Fed. Cl. 457, 461 (1993); see also Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 720 (2009) ("The special masters were free to reach different conclusions based on the same evidence.") (citing Sharpnack, 27 Fed. Cl. at 461). Thus, special masters' adjudications on entitlement do not dictate outcome in other cases. Boatmon v. Sec'y of Health & Human Servs., 941 F.3d 1351, 1358 (Fed. Cir. 2019).

The possibility that different finders of fact can reach different outcomes on entitlement also appears to extend to questions of reasonable basis. See Silva v. Sec'y of Health & Human Servs., 108 Fed. Cl. 401, 402 (2012) (stating, before Simmons, Cottingham, and James-Cornelius that the Vaccine Act gives a special master "maximum" discretion in determining reasonable basis). This discretion to weigh evidence differently and to reach different conclusions regarding reasonable basis (or the lack thereof) means that decisions of other special masters do not constitute binding precedent.

While special masters seem to enjoy latitude in how they evaluate evidence, special masters must conform to legal standards set by appellate authorities. After the Federal Circuit's remand in Ms. Cottingham's case, the parties continued to dispute at least two related questions of law. First, the parties offered competing understandings of the terms "feasibility" and "feasible" in the context of reasonable basis. Second, the parties differed on whether, to establish a reasonable basis for the claims set forth in a petition, petitioners must present some evidence that a vaccination caused this particular vaccinee's problem via a treating doctor or retained expert.

Ms. Cottingham maintained that a claim possesses reasonable basis when a petitioner: "(1) receives a covered vaccination; (2) produces medical records demonstrating the complaints alleged; and (3) it is feasible to think that the documented complaints could have been caused by the vaccination at issue." Pet'r's Br., filed Aug. 9, 2021, at 5. While at this portion of her brief Ms. Cottingham cites no authority for this definition, she later relates her understanding of "feasible" to the Federal Circuit's statement that "[Ms. Cottingham's] injuries paired with the Gardasil package insert thus constitute a minimum circumstantial,

objective evidence supporting causation." Id. at 5 (quoting Cottingham, 917 F.3d at 1346).

The Secretary used "feasible" differently. To the Secretary, a claim may satisfy the reasonable basis standard when a petitioner can "point to some objective evidence to support each of the Althen prongs because an absence of evidence as to any necessary element of the petitioner's prima facie case necessarily means the claim has no feasibility of success." Resp't's Br., filed Aug. 9, 2021, at 5. The Secretary analogized the reasonable basis standard to the summary judgment standard in which a failure of proof on an element of a nonmoving party's case warrants judgment as a matter of law. Id. (citing Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)); see also id. at 8 (maintaining that before Ms. Cottingham filed a motion to dismiss her case voluntarily, the Secretary was entitled to judgment as a matter of law).

The Secretary's linking "feasibility" to the prongs found in Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1278 (Fed. Cir. 2005), introduced the second legal question on which the parties differed. Ms. Cottingham argued: "Delving into a causation under Althen is an improper elevation of the reasonable basis standard. . . . [Petitioner] does not need to prove either Althen prongs 1 or 2 by a preponderance of evidence." Pet'r's Br. at 5. Ms. Cottingham expanded this argument to include the timing prong of Althen as well: "Requiring [petitioner] to satisfy Althen prong 3 for a finding of reasonable basis would constitute legal error." Id. at 10.

The Secretary offered a different view. To satisfy the reasonable basis standard, "a petitioner must present objective evidence to support each of the Althen prongs, along with the other essential elements laid out in Section 11(c) of the [Vaccine] Act." Resp't's Br. at 5. The Secretary's conclusion is based upon the Federal Circuit's summary of what the Vaccine Act (42 U.S.C. § 300aa–11(c)(1)) requires in a petition. Id. at 3. In particular, the third of five statutory elements requires that the vaccinee have "sustained . . . an injury . . . that was caused by the vaccine." Cottingham, 971 F.3d at 1345-46. The Federal Circuit mandated that Ms. Cottingham "must point to evidence of a causal relationship between the administration of the vaccine and her injuries in order to establish that a reasonable basis for the claim existed when the petition was filed." Id. at 1346. The "causal relationship," in turn, is defined as the three-part test in Althen, 418 F.3d at 1278.

Althen's three-part test might take significance with respect to prong 2. Prong 2 of Althen requires, for purposes of entitlement, that a petitioner

demonstrate with preponderant evidence "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." 418 F.3d at 1278. The Secretary argued that "the record in this case is devoid of *any* evidence to address the second prong of the Althen test. Accordingly, petitioner has failed to present even a *scintilla* of evidence to address an essential element of her claim." Resp't's Br. at 3. Similarly, during the December 14, 2020 oral argument conducted before the Federal Circuit's opinion in James-Cornelius, the Secretary maintained that in an off-Table case, petitioners are required to have "some medical expert, whether that's a treating physician or an expert, tie the vaccination to the alleged injuries," Tr. 67, and that the lack of a report from a treating doctor or retained expert affects the reasonable basis analysis.

While the January 7, 2021 decision evaluated those legal arguments, the undersigned did not have the benefit of the Federal Circuit's opinion in James-Cornelius.

Preliminarily, although the parties used the terms "feasibility" and "feasible" to evaluate reasonable basis, the appropriateness of this terminology is unclear. Simmons directs special masters to look at objective evidence. Simmons, 875 F.3d at 635-36. The Federal Circuit in Simmons did not use the terms "feasibility" or "feasible." Similarly, the Federal Circuit in Cottingham also did not use the terms "feasibility" or "feasible." In James-Cornelius, the Federal Circuit used the term "feasible" only in summarizing the special master's decision.

Cottingham advances the jurisprudence around reasonable basis by directing special masters to look for Simmons's "objective evidence" in the elements comprising a petitioner's case-in-chief, that is, the five elements listed 42 U.S.C. § 300aa–11(c)(1). One of those statutorily required elements (paragraph (C)) is a showing of causation.

For cases in which petitioners (like Ms. Cottingham) allege an off-Table injury, the Federal Circuit defined how petitioners demonstrate causation-in-fact in Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1278 (Fed. Cir. 2005). According to Hibbard v. Secretary of Health & Human Services, 698 F.3d 1355, 1366 (Fed. Cir. 2012), the en banc Federal Circuit opinion in Cloer v. Secretary of Health & Human Services, 654 F.3d 1322, 1334 n.4 (Fed. Cir. 2011), "characterized Althen as setting forth 'three pleading requirements for a non-Table

injury petition.'"[9] Cloer, itself, explained that in off-Table cases, "a petitioner must file an affidavit and supporting documentation demonstrating that the 'vaccine-related injury' for which compensation is sought was caused by a vaccine." Cloer, 654 F.3d at 1334.

It would seem that the Federal Circuit's statement that Ms. Cottingham "must point to evidence of a causal relationship between the administration of the vaccine and her injuries in order to establish that a reasonable basis for the claim existed when the petition was filed," Cottingham, 917 F.3d at 1346, must be importing the Althen factors into the reasonable basis analysis. However, Cottingham does not refer to Althen at all.

As set forth above, the Secretary's position was (at least before James-Cornelius) that an analysis of the "objective evidence" must account for all the Althen factors. Ms. Cottingham's position on this point, however, is not clear due to some rhetorical sleight-of-hand. Ms. Cottingham argues in the reasonable basis context, a petitioner "does not need to prove either Althen prongs 1 or 2 *by a preponderance of evidence*." Pet'r's Br. at 5 (emphasis added). Additionally, Ms. Cottingham maintains that "[r]equiring [petitioner] to *satisfy* Althen prong 3 for a finding of reasonable basis would constitute legal error." Id. at 10 (emphasis added).

What Ms. Cottingham has stated is literally accurate, but misdirected. The preponderance of evidence standard is the standard by which special masters determine whether petitioners are entitled to compensation. 42 U.S.C. § 300aa–13. The preponderance of the evidence standard is not the correct standard for determining whether petitioners established a reasonable basis for the claims set forth in the petition. By referring to the "preponderance of the evidence" standard, Ms. Cottingham has muddied the waters on the question as to whether the "more than a mere scintilla of evidence" standard applies to each of the Althen prongs.

Given Cottingham's focus on "causation," as well as the wide-spread acceptance of the Althen three-part test for causation-in-fact cases, the undersigned holds that an examination of reasonable basis should include an analysis to see whether objective evidence supports a petition's claim with respect to each of the

[9] While the Althen test might be pleading elements, Ms. Cottingham's petition does not include assertions about specific parts of the Althen test.

Althen prongs.[10] This holding is consistent with a conclusion of a judge of the Court of Federal Claims in an opinion issued after Simmons but before Cottingham. The Court reasoned: "Because causation was a necessary element of [the petitioner's] claim, she had to provide some evidence of a causal relationship between administration of the vaccine and her injuries to establish a reasonable basis for the claim. The type and amount of such evidence has never been delineated with specificity, and it can vary depending on the vaccine administered and the injury suffered. Nonetheless, it can be said with confidence that the quantum of evidence of causation to show reasonable basis is markedly less than that needed to prove entitlement." Bekiaris v. Sec'y of Health & Human Servs., 140 Fed. Cl. 108, 114 (2018). The evidentiary support on any of the three Althen prongs does not have to satisfy the preponderance of the evidence standard. But, the evidentiary support on all the three prongs must be "more than a mere scintilla."

The statement that the reasonable basis analysis should encompass each of the Althen prongs is a small clarification in the sense that it would seem that the causation element found in section 11(c)(1)(C) would be undefined without the Althen test. Althen's interpretation of the causation standard illuminates the meaning of the Vaccine Act. To jettison the Althen test for purposes of reasonable basis would leave litigants and special masters in the dark.

While in the January 7, 2021 decision the undersigned held that as part of the analysis of Althen prong 2 the undersigned could see whether petitioner presented medical records or medical opinions, Fourth Fee Decision, 2021 WL 347020, at*18-19, this statement was made without the benefit of the Federal Circuit's opinion in James-Cornelius. There, the Federal Circuit stated: "[A]bsence of an express medical opinion on causation is not necessarily dispositive of whether a claim has a reasonable basis." James-Cornelius, 984 F.3d at 1379.

Similarly, in reviewing the January 7, 2021 decision, the Court of Federal Claims held that the undersigned erred in requiring that Ms. Cottingham supply a medical or expert opinion on causation to establish a reasonable basis. Fourth Opinion, 2021 WL 3085502, at *8. In accord with these dictates from appellate authorities, the lack of a direct statement from a treating doctor and/or a doctor

[10] If Cottingham intended the causation element for off-Table cases to mean something other than the Althen test, Cottingham did not set forth any alternative way of reviewing causation.

retained for purposes of litigation is not a factor affecting the analysis of reasonable basis.

The Court's July 21, 2021 opinion expands upon the meaning of the term "scintilla of evidence" by discussing a case from the Federal Circuit and a case from the Fourth Circuit. The Court stated:

> In Saposnekoo v. Department of Navy, the Federal Circuit noted that "Black's Law Dictionary (4th ed. 1951) defines 'scintilla of evidence' as 'a spark of evidence . . . . A metaphorical expression to describe a very insignificant or trifling item or particle of evidence . . . .'" 835 F.2d 871, 871 n.2 (Fed. Cir. 1987) (unpublished table decision) (alteration in original). The Federal Circuit in Saposnekoo found that it would be improper to "equate substantial evidence 'with more than a scintilla of evidence,'" because the standard for substantial evidence "is higher than that minimal one [more than a scintilla]—it must be 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion,' or evidence 'enough to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury.'" Id. at 871 (quoting Consolo v. Fed. Mar. Comm'n, 383 U.S. 607, 620 (1966)); see also Arendi S.A.R.L. v. Apple Inc., 832 F.3d 1355, 1360 (Fed. Cir. 2016).
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> * * *
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> Determining what constitutes "more than a mere scintilla" of evidence is a daunting task. As the Fourth Circuit recently noted:
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> > Standards are easy to recite, but harder to apply. Part of that difficulty, at least for summary judgment standards, lies with confusing terminology like "a scintilla of evidence." After all, what in the world is a "scintilla?" Given federal courts, as noted above, require more than a scintilla of evidence to avoid summary judgment, understanding what a scintilla is seems necessary to understand if a party has exceeded it. But dating back to the nineteenth century, courts have struggled with the

> "distinction between what is a scintilla" and what is not. Boing v. Raleigh & G.R. Co., 87 N.C. 360 (N.C. 1882) (remarking that the distinction "is so narrow that it is often very difficult for a court to decide upon which side of the line" evidence falls). . . . Compare Kurtz v. Fels, 63 Wash. 2d 871, 389 P.2d 659, 663 (1964) (holding that proof beyond a mere scintilla requires "facts to be assessed by the senses" and something "tactile" rather than calculations), with Gibson v. Epting, 426 S.C. 346, 827 S.E.2d 178, 181 (2019) (describing scintilla as "a perceptible amount" and "not something conjured up by the shadows"), and Davies v. McDowell Nat. Bank, 407 Pa. 209, 180 A.2d 21, 30 (1962) (dissent) ("'Scintilla' means spark.").
>
> Sedar v. Reston Town Ctr. Prop., LLC, 988 F.3d 756, 761 n.3 (4th Cir. 2021). In Sedar, the Fourth Circuit ruled that summary judgment was not appropriate because the appellant had adduced more than a mere scintilla of evidence, which the Court characterized as "evidence beyond speculation that provides a sufficient basis for a reasonable inference of causation." Id. at 765 (quoting Penley v. McDowell Cnty. Bd. of Educ., 876 F.3d 646, 655 (4th Cir. 2017)).

Fourth Opinion, 2021 WL 3085502, at *4-5.

The Court then listed various factors for consideration, including "the import of James-Cornelius," "the import of the Gardasil package insert, considering 21 C.F.R. § 201.57," "the policies of the Vaccine Act encouraging petitioners to file petitions and obtain qualified counsel to assist them," possibly the Althen factors, and "other pertinent factors such as the novelty of the vaccine." Id. at *8.

IV. Topics the Court of Federal Claims Identified

A. Policy

The Court's July 21, 2021 Opinion directed the undersigned to consider "[t]he policies of the Vaccine Act encouraging petitioners to file petitions and obtain qualified counsel to assist them." Fourth Opinion, 2021 WL 3085502, at *8 (Fed. Cir. July 21, 2021). This topic is both simple and complicated.

The simple answer is that a policy to encourage petitioners to obtain qualified counsel supports paying all attorneys in all cases. Such a broad generalization encompasses paying Mr. Downing in Ms. Cottingham's case and the way to accomplish that policy goal is to find reasonable basis.

However, a more complete answer might be more complicated in at least two respects. First, the Secretary argues that the policy of encouraging attorneys to represent petitioners should not be a part of the undersigned's analysis as to whether reasonable basis supported the claims set forth in Ms. Cottingham's petition. The Secretary's argument starts from the point settled in Simmons that the reasonable basis standard is met with objective evidence. Resp't's Br., filed Aug. 8, 2021, at 6; see also Simmons, 875 F.3d at 636. From that beginning, the Secretary reasons that "including policy considerations in the reasonable basis analysis cannot be squared with the holding, affirmed in both James-Cornelius and this case, that reasonable basis is only established with objective evidence." Resp't's Br. at 7.[11]

It would seem that the appellate courts in interpreting the Vaccine Act's "reasonable basis" provision might weigh the policy consideration in setting a bar or standard by which special masters should evaluate arguments regarding reasonable basis. For example, there remains, at least to the undersigned, uncertainty over the evidentiary standard. Clearly, the reasonable basis standard does not require petitioners to present preponderant evidence. Chuisano v. Sec'y of Health & Human Servs., No. 07-452V, 2013 WL 6234660, at *13 (Fed. Cl. Spec. Mstr. Oct. 25, 2013), mot. for rev. denied, 116 Fed. Cl. 276 (2014). At the other end of the spectrum, Simmons teaches that a case with zero evidence fails the reasonable basis standard. Simmons v. Sec'y of Health & Human Servs., 128 Fed. Cl. 579, 583 (2016), aff'd, 875 F.3d 632 (Fed. Cir. 2017). But, the undersigned respectfully submits, the strength and quality of objective evidence can range from barely above a scintilla to nearly a preponderance. While the Federal Circuit in Cottingham stated that "more than a mere scintilla but less than a preponderance of proof could provide sufficient grounds for a special master to find reasonable basis," 971 F.3d at 1346, did the Federal Circuit also determine, as a matter of law,

[11] The Secretary extends this argument to say "the reasonable basis standard should be described as a 'totality of the evidence' test, rather than a 'totality of the circumstances' test. If subjective considerations are excluded from the analysis, then by definition, the analysis cannot include a totality of the circumstances." Resp't's Br. at 8. However, as Ms. Cottingham correctly stated in her reply, the "Federal Circuit, in this case, has already rejected Respondent's argument." Pet'r's Reply, filed Aug. 23, 2021, at 3.

that in every case in which a petitioner presents more than a mere scintilla of evidence, the special master must find reasonable basis? If the presence of more than a mere scintilla of evidence does not confer reasonable basis automatically, then where in the span between "more than a scintilla" and "less than a preponderance" does the line rest? Conceivably, an appellate court might set the line nearer to the scintilla level. Or an appellate court might set the line closer to the preponderance level. These are choices for an appellate court. Then, after the appellate court determines the standard, the special master determines how the evidence weighs. See Althen, 418 F.3d at 1280 ("The special master's role is to apply the law.").

The second complication in examining the policies animating the Vaccine Act and the reasonable basis standard is the Supreme Court's statement that "it is quite mistaken to assume, as petitioners would have us, that 'whatever' might appear to 'further[] the statute's primary objective must be the law.' . . . Legislation is, after all, the art of compromise, the limitations expressed in statutory terms often the price of passage, and no statute yet known 'pursues its [stated] purpose [] at all costs.'" Henson v. Santander Consumer USA Inc., 137 S. Ct. 1718, 1725 (2017). In a relatively recent order denying a rehearing en banc, six judges of the Federal Circuit quoted this passage. Kisor v. McDonough, 995 F.3d 1347, 1351-52 (Fed. Cir. 2021).

A review of Federal Circuit jurisprudence shows that the Federal Circuit has not always interpreted the attorneys' fees provision in a way that promotes payment of attorneys to foster representation of petitioners. A prominent example is Simmons.

In Simmons, the petitioner's attorney filed a petition to prevent the statute of limitations from expiring. 875 F.3d at 634. The special master justified a finding of reasonable basis on the looming statute of limitations. Id. at 635 (citing 2016 WL 2621070, at *3). The special master's reliance on the statute of limitations was similar to reasoning in other cases. See, e.g., Hippo v. Sec'y of Health & Human Servs., No. 10-462V, 2012 WL 1658252 (Fed. Cl. Spec. Mstr. Apr. 18, 2012); Lamar v. Sec'y of Health & Human Servs., No. 99-584V, 2008 WL 3845157 (Fed. Cl. Spec. Mstr. July 30, 2008); Hamrick v. Sec'y of Health & Human Servs., No. 99-683V, 2007 WL 4793152 (Fed. Cl. Spec. Mstr. Nov. 19, 2007); Peca v. Sec'y of Health & Human Servs., No. 90-122V, 1992 WL 30423 (Fed. Cl. Spec. Mstr. Feb. 3, 1992). (The pending statute of limitations also happens to be the primary argument that Ms. Cottingham initially advanced in support of her claim for reasonable basis. Pet'r's 1st Mot. for Rev. at 2-6.) But,

the judge at the Federal Circuit rejected this argument. Simmons v. Sec'y of Health & Human Servs., 128 Fed. Cl. 579, 584 (2016).

At the Federal Circuit, the petitioner-appellant in Simmons advanced an argument based upon policy to justify reliance on a looking statute of limitations:

> If Judge Firestone's ruling stands, on the other hand, it would have a chilling effect on any petitioner who seeks representation on the eve of the statute of limitations by restricting the pool of competent counsel willing to represent such petitioners. This would, at best, create an influx of *pro se* petitioners into the Program and, at worst, result in meritorious petitions being left unfiled, thereby thwarting a primary purpose of the Program that vaccine-injured individuals have access to competent counsel.

Br. of Pet'r-Appellant at 19, No. 2017-1405, 2017 WL 1033932 (Fed. Cir. Mar. 6, 2017). Nevertheless, despite the plea that an adverse outcome at the Federal Circuit would deprive petitioners of access to competent counsel, the Federal Circuit affirmed the denial of fees. 875 F.3d at 636.

Another example concerns the hourly rate at which attorneys are compensated. At one time, attorneys representing petitioners requested that special masters compensate them at rates set out in the Laffey matrix for attorneys in Washington, DC. The Laffey matrix rates exceeded, sometimes greatly exceeded, the rate at which the attorney was typically paid. After a special master found that the Laffey matrix rates were not useful, a case reached the Federal Circuit. The petitioner-appellant argued: "The use of the Laffey Matrices . . . will have the effect of attracting counsel who are highly capable and can help fulfill the important purposes of the Vaccine Act." Br. of Pet'r-Appellant at 36, No. 2010-5093, 2010 WL 2661681 (Fed. Cir. June 16, 2010). While the Federal Circuit acknowledged that the petitioner "argues that there are strong policy rationales for using the Laffey and Adjusted Laffey matrices," the Federal Circuit upheld the special master's decision not to compensate attorneys at the Laffey rates. Rodriguez v. Sec'y of Health & Human Servs., 632 F.3d 1381 (Fed. Cir. 2011).

A third example of a Federal Circuit opinion that did not advance the policy goal of paying attorneys to foster a bar of competent attorneys is Perreira. There, the petitioners paid an expert to review the case and to testify at a hearing. 33 F.3d at 1376. Despite an expert's testimony, the chief special master found that the petitioners lacked a reasonable basis to proceed to a hearing. On appeal to the

Federal Circuit, the petitioners-appellants argued "that the intent of Congress is violated by requiring counsel to support expert opinions as a requisite to receiving attorneys fees and costs under the Act." Id. at 1376. The Federal Circuit rejected this argument, stating "Congress must not have intended that every claimant, whether being compensated or not under the Vaccine Act, collect attorney fees and costs by merely having an expert state an unsupported opinion that the vaccine was the cause in-fact of the injury." Id. at 1377.

Simmons, Rodriguez, and Perreira, thus, serve as examples in which the Federal Circuit have turned away efforts to advance one purpose of the Vaccine Act, which is to attract qualified attorneys to represent petitioners. To be sure, other cases buttressed this policy. E.g., Avera v. Sec'y of Health & Human Servs., 515 F.3d 1343, 1351 (Fed. Cir. 2008) (holding that petitioners may receive awards of attorneys' fees and costs on an interim basis); Sanders v. Sec'y of Health & Human Servs., 25 F.3d 1031, 1035-36 (Fed. Cir. 1994) (holding that petitioners who rejected the entitlement judgment may still receive a separate decision awarding them attorneys' fees and costs).

For their part, the parties offer various arguments why a finding regarding (the lack of) reasonable basis would or would not advance policies at the foundation of the Vaccine Act. Ms. Cottingham argues that the structure in place for awarding attorneys' fees is set up to ensure that petitioners in the Program have access to competent counsel and states that a finding against reasonable basis in this case will have a "chilling effect" on this access. Pet'r's Br., filed Aug. 9. 2021, at 6-8. The Secretary argues in response that the reasonable basis limitation on awards of attorneys' fees serves that competing policy goal of encouraging diligence by attorneys in the Program and ensuring attorneys "only bring claims that have some basis in science, fact, and law." Resp't's Br., filed Aug. 9, 2021, at 3. The Secretary also points to statistics to show that there has been no practical effect on petitioners' access to counsel in the Program, which Ms. Cottingham challenged in her reply. Id. at 4; Pet'r's Reply, filed Aug. 23, 2021, at 3-4. Ultimately, the Secretary also argues that policy considerations are, by definition, subjective evidence, which should not be considered in evaluating reasonable basis given the requirement of "objective evidence" set out in Simmons, Cottingham, and James-Cornelius. Resp't's Br. at 6.

As a judicial officer whose duties are solely to oversee and to adjudicate claims in the Vaccine Program, the undersigned has seen a few cases in which experienced attorneys have brought cases that lacked a reasonable basis. See, e.g., Gordon v. Sec'y of Health & Human Servs., No. 18-40V, 2021 WL 1957509 (Fed. Cl. Spec. Mstr. Apr. 16, 2021) (finding a lack of reasonable basis where petitioner

failed to submit proof of vaccination). On the other hand, the undersigned would be hard-pressed to identify any resolved cases in which a pro se petitioner had even a vaguely meritorious claim. This observation suggests, but certainly does not prove, that people with valid claims that a vaccine harmed them are finding attorneys to represent them.[12]

On the whole, the policies animating the Vaccine Program have little, if any, effect on the outcome. If Ms. Cottingham presents sufficient evidence to fulfill the reasonable basis standard, then she will receive attorneys' fees and costs.[13] If Ms. Cottingham does not present sufficient evidence for reasonable basis, then she will not receive attorneys' fees and costs.[14]

B. Novelty

The Court's July 7, 2021 Opinion directed the undersigned to consider novelty. Fourth Opinion, 2021 WL 3085502, at *8. The parties have spent relatively little time on this topic.

In her brief in response to the most recent remand, Ms. Cottingham stated that the HPV vaccine is the most novel vaccine dealt with in the Vaccine Program and points to exhibits 11-15 as examples of emerging research findings that support the reasonable basis of her claim. Pet'r's Br., filed Aug. 9, 2021, at 8-11. The Secretary briefly addressed the issue of novelty by stating that, unlike types of claims routinely found to be meritorious, the claim in this case should require some specific evidence of causation to show reasonable basis. Resp't's Br., filed Aug. 9, 2021, at 7 n.4. Ms. Cottingham responded by stating in her reply that, conversely, the novelty of the claim combined with the evidence submitted should only help produce a finding of reasonable basis. Pet'r's Reply, filed Aug. 23, 2021, at 2.

Although the Federal Circuit stated that special masters may consider the "novelty" of a vaccine, Cottingham, 971 F.3d at 1347, how "novelty" fits within a scheme in which decisions about reasonable basis are based upon objective

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[12] A confounding factor is that some people with valid claims may not file claims in the Vaccine Program and, thus, remain unknown.

[13] The Secretary's suggestion that a special master might (a) find reasonable basis and (b) still decline to award attorneys' fees and costs is discussed in section VII, below.

[14] The undersigned hopes that it is unnecessary to say that neither animosity nor favoritism toward counsel plays any role in the adjudications. Both Mr. Downing and Mr. Johnson advocate for their clients passionately, effectively, and ethically.

evidence is not clear. Despite the parties' relative lack of attention on novelty, some objective evidence about the HPV vaccine is available.

In the May 27, 2005 issue of Morbidity and Mortality Weekly Report, The Centers for Disease Control and Prevention recommended the HPV vaccine and on April 20, 2007, the Secretary announced that the Vaccine Program would compensate people harmed by the HPV vaccine. 72 Fed. Reg. 19937. According to information from the Clerk's Office, from that date until October 30, 2015, 209 cases were filed using a nature of suit code for the HPV vaccine. Ms. Cottingham filed her petition on October 30, 2015. So, in other words, before Ms. Cottingham filed her petition, approximately 200 other petitioners filed claims based upon the HPV vaccine.

"Novelty," to Ms. Cottingham, may refer to the number of studies that evaluated the safety of the HPV vaccine. However, for "objective" evidence, the present record contains relatively little information about the ways in which the federal government determined that the HPV vaccine was safe enough to authorize.[15] Ms. Cottingham, as discussed below, has submitted five medical articles about the HPV vaccine. From the undersigned's experience, the undersigned is aware of additional studies that are not part of the record. See Tr. 40 (discussing Chao article).

While it is easy to imagine that the upcoming years will bring new studies involving the HPV vaccine, predicting what those studies will show is difficult. Future studies might reveal that the HPV vaccine causes more adverse reactions than previously suspected. Or, the future studies might demonstrate that the HPV vaccine is safe and causes very few, if any, adverse reactions.[16] It would seem that basing a decision about the reasonable basis for the claims set forth in Ms. Cottingham's petition on speculation about future studies would not be consistent with the instruction to rely upon objective evidence.

[15] The package insert compares a 9-valent HPV vaccine to the original quadrivalent HPV vaccine. See exhibit A.

[16] Delaying adjudication of claims of entitlement has not always worked to the benefit of petitioners. Snyder v. Sec'y of Health & Human Servs., No. 02-162V, 2009 WL 332044, at *147 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) ("The science has developed in the intervening years, but not in the OAP petitioners' favor."), mot. for rev. denied, 88 Fed. Cl. 706 (2011).

C. James-Cornelius

The Federal Circuit's opinion in James-Cornelius brings forward at least three points warranting consideration. However, on a critical point, the guidance remains unclear.

First, James-Cornelius held that a petitioner's affidavit about when he or she experienced various symptoms constitutes a type of objective evidence that a special master must consider in evaluating reasonable basis. One reason the Federal Circuit vacated the judgment was to allow the special master to consider the petitioner's affidavit. 984 F.3d at 1380.

This holding, while important in other cases, has little effect on Ms. Cottingham's case. The undersigned has accepted, for purposes of determining reasonable basis, the accuracy of Kaci Cottingham's affidavit attesting that she began having regular weekly headaches and occasional low-grade fever starting on November 1, 2012.[17] Exhibit 1 ¶ 5. In this sense, Ms. Cottingham's affidavit roughly aligns with the medical records from Vestavia Pediatrics, which suggest that the symptoms started slightly later. See exhibit 3 at 87-88. Thus, the undersigned respectfully suggests that the value of Ms. Cottingham's affidavit is not the source of trouble.

Second, James-Cornelius held that the "absence of an express medical opinion on causation is not necessarily dispositive of whether a claim has a reasonable basis, especially when the case is in its early stages and counsel may not have had the opportunity to retain qualified experts." 984 F.3d at 1379. The key word appears to be "necessarily." In the Secretary's response to the most recent motion for review, the Secretary stated that the Federal Circuit "panel only held that a causation opinion is not 'necessarily' required to establish reasonable basis, which essentially means that, in some cases, a causation opinion *is* required." Resp't's Resp. to Mot. for Rev., filed Mar. 8, 2021, at 18. In her reply, Ms. Cottingham did not address this argument. See Pet'r's Reply, filed Mar. 15, 2021.

To the undersigned, the Secretary's interpretation of the Federal Circuit's phrase "absence of an express medical opinion on causation is not necessarily dispositive of whether a claim has a reasonable basis" seems persuasive and

[17] The presence of black outs at this time, as stated in Ms. Cottingham's affidavit, is less clear from the medical records. However, the undersigned accepts Ms. Cottingham's statement regarding onset of headaches and an occasional low-grade fever.

logical. By inserting the adverb "necessarily," the Federal Circuit seems to be implying that the lack of an express medical opinion could be at least one point in determining whether reasonable basis supports the claims set forth in the petition. But, it is unclear when special masters should consider the lack of "express medical opinion on causation."[18] Thus, to extend to Ms. Cottingham the benefit of the doubt and to minimize potential issues for further appellate review, the undersigned will not consider the "absence of an express medical opinion on causation."

Third, James-Cornelius also remanded the case with instructions for the special master to reevaluate the evidence. This outcome seems consistent with the outcome in the present case.

While the Court's July 6, 2021 Opinion directed the undersigned to consider the effect of the Federal Circuit's opinion in James-Cornelius, the special master assigned to James-Cornelius issued a decision on remand on July 27, 2021. See Pet'r's Br., filed Aug. 9, 2021, at 4 (citing this decision). There, the special master construed the Federal Circuit's opinion as holding that the Federal Circuit determined petitioner "ha[d] presented multiple pieces of objective evidence and that those pieces of evidence amount to 'more than a mere scintilla' of evidence sufficient to establish reasonable basis." James-Cornelius v. Sec'y of Health & Human Servs., No. 17-1616V, 2021 WL 3598347, at *2 (Fed. Cl. Spec. Mstr. July 27, 2021).

[18] The Federal Circuit's potential limitation "especially when the case is in its early stages and counsel may not have had the opportunity to retain qualified experts" also raises questions regarding how or whether to consider this evidence (or lack thereof). One question is whether the case enters an "early stage[]" when the petitioner first consults the attorney or whether the case starts an "early stage[]" after the litigation is initiated by filing the petition. See Austin v. Sec'y of Health & Human Servs., No. 10-362V, 2013 WL 659574, at *9-10 (Fed. Cl. Spec. Mstr. Jan. 31, 2013) ("There exists a tension between supporting the policy behind the award of fees to unsuccessful litigants and discouraging 'gaming the system.'"). Another question is what happens when counsel has had the opportunity to retain qualified experts. In Ms. Cottingham's case, Mr. Downing did consult experts who declined to offer an opinion supporting causation. Third, if reasonable basis sets a standard that is met with evidence, does that evidentiary standard change because the case ages? Finally, any extended discussion of counsel's (lack of) efforts to retain a qualified expert seems dangerously close to considering the conduct of any attorney during the analysis of reasonable basis. See James-Cornelius, 984 F.3d at 1381 (finding that the special master misapplied the reasonable basis standard "[b]y going beyond the allegations an evidence in the petition, and instead looking to counsel's conduct and state of mind").

But, the undersigned has already interpreted the Federal Circuit's opinion in this case as permitting the undersigned discretion in determining whether the objective evidence supported the claims in Ms. Cottingham's petition. Fourth Fees Decision, 2021 WL 347020, at *15. In Ms. Cottingham's fourth motion for review, she did not argue that the undersigned's interpretation of the panel's opinion was erroneous. See Pet'r's Mot., filed Feb. 5, 2021. Thus, the special master's July 27, 2021 decision in James-Cornelius does not control the outcome of this case.[19]

D. Package Insert

The Federal Circuit remanded, in part, for the special master to evaluate the package insert in determining whether a reasonable basis supported the claims set forth in Ms. Cottingham's petition. The Federal Circuit indicated that the package insert, as part of the record, should have been analyzed explicitly. Cottingham, 971 F.3d at 1346. Thus, the Fourth Fees Decision examined this issue across five pages and that analysis is repeated:

1. Citations to Product Insert in this Litigation

As discussed in the procedural history, Ms. Cottingham did not submit the package insert during her case-in-chief regarding entitlement. She also did not file the product monograph to support her argument regarding reasonable basis, although Ms. Cottingham provided an internet link to it. Pet'r's Mot. for Attorneys' Fees and Costs, filed Oct. 26, 2016, at 4. The Secretary, however, provided a product monograph as exhibit A. Resp't's Resp., filed Nov. 14, 2016,

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[19] In addition to the procedural differences, the evidence supporting reasonable basis was much stronger in James-Cornelius, according to Mr. Downing, the attorney representing petitioners in both cases. During the oral argument in James-Cornelius, he told the Federal Circuit panel: "This case is even stronger than Cottingham. Here, after the symptoms were present for an extended period of time, . . . after clinical examination, the treating physician contemplated filing a VAERS form . . . indicating that at a minimum, . . . this physician is contemplating reporting a vaccine adverse event to the CDC. That is far beyond the evidence that was present in Cottingham and it may very well be the most important piece of evidence here." Oral Argument at 6:05, James-Cornelius v. Sec'y of Health & Human Servs., 984 F.3d 1374 (2021) (No. 2019-2404), http://www.cafc.uscourts.gov/oral-argument-recordings?title=&field_case_number_value=2019-2404&field_date_value2%5Bvalue%5D%5Bdate%5D=. On rebuttal, Mr. Downing reiterated: "This case is very similar to Cottingham . . . I think this case is actually stronger than Cottingham given the treating doctor's contemplation of reporting a vaccine adverse event to the CDC." Id. at 35:02.

at 5 n.1. As mentioned in the December 14, 2020 oral argument, exhibit A is the product monograph for Gardasil 9. Tr. 27. Ms. Cottingham did not receive this vaccine. She received a quadrivalent version. Exhibit 3 at 100. However, the "vaccines are manufactured similarly and contain the same antigens from HPV types 6, 11, 16, and 18," exhibit A at 9, and the parties appear to have overlooked any difference between the two types of vaccines.

Thereafter, the product monograph appears sporadically in briefing from Ms. Cottingham. Ms. Cottingham did not cite the product monograph in briefs associated with her first motion for review. See Pet'r's Mot. for Rev., filed Apr. 27, 2017; Pet'r's Reply, filed June 2, 2017. In defending the Second Fees Decision against the Secretary's motion for review, Ms. Cottingham relied upon the product insert to show autonomic dysfunction occurring outside of a 15-minute window. Pet'r's Resp. to Mot. for Rev., filed Feb. 5, 2018, at 10. In challenging the Third Fees Decision, which had found no reasonable basis, Ms. Cottingham did not cite the product monograph. See Pet'r's Mem. Supporting Pet'r's 2d Mot. for Rev., filed July 19, 2018; Pet'r's Reply, filed Aug. 27, 2018. In sum, across five briefs to the Court of Federal Claims filed in conjunction with three motions for review, Ms. Cottingham alluded to the product monograph once.

At the Federal Circuit, Ms. Cottingham argued that the product monograph for the HPV vaccine "connect[s]" the HPV vaccine with "headache, nausea, syncope, abdominal pain and dizziness." Br. of Pet'r-Appellant, filed May 14, 2019, at 23. However, the Secretary did not respond to Ms. Cottingham's assertion by discussing the product monograph. See Br. of Resp't-Appellee, filed June 5, 2019.

In the Federal Circuit's Opinion, the Federal Circuit ruled that the package insert merited discussion. The Federal Circuit declared that "The Gardasil package insert links [Ms. Cottingham's] injuries to adverse reactions associated with Gardasil's administration." Cottingham, 917 F.3d at 1346.

In sending the case back to the special master, the Federal Circuit corrected a legal error the undersigned made. Before Cottingham, the undersigned believed that the evidence that could support a finding of reasonable basis consisted of medical records or medical opinions. For a lengthy, if erroneous, discussion, see Silva v. Sec'y of Health & Human Servs., No. 10-101V, 2012 WL 2890452 (Fed. Cl. Spec. Mstr. June 22, 2012) (discussing 42 U.S.C. § 300aa–11(c)), mot. for rev. denied, 108 Fed. Cl. 401 (2012); see also Carter v. Sec'y of Health & Human Servs., No. 16-852V, 2018 WL 6322447, at *10 (Fed. Cl. Spec. Mstr. Oct. 16, 2018) (finding petitioner did not satisfy the reasonable standard when the child's

treating doctors did not link vaccinations to developmental delay and petitioner did not file an expert report). Under this erroneous understanding, the undersigned did not discuss the package insert because the package insert constitutes neither a "medical record" nor a "medical opinion."

Relatedly, the undersigned also understood that special masters could disregard medical articles about which "there was not testimony offered by any expert as to the validity or import of such article." Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1347 (Fed. Cir. 2010). Because neither Ms. Cottingham nor the Secretary had supplied an expert to explain the significance of the product monograph, it appeared that the product monograph was not a meaningful aspect of Ms. Cottingham's argument that a reasonable basis supported the claims set forth in her petition. Cf. Moriarty v. Sec'y of Health & Human Servs., 844 F.3d 1322, 1330-31 (Fed. Cir. 2016) (requiring special master to address articles to which an expert referred in his report). However, pursuant to the Federal Circuit's Opinion in Cottingham, the parties may introduce evidence, potentially favoring or potentially undermining a finding of reasonable basis for the claims set forth in the petition, that is not a medical record or a medical opinion.

After the Federal Circuit's correction, the undersigned directed the parties to discuss the product insert. Order, issued Oct. 15, 2020, ¶ 7. The parties responded in their briefs. Given this history of how the product insert was used and not used in Ms. Cottingham's case, the undersigned next discusses how product inserts are created.

2. Creation of Product Inserts[20]

Before a manufacturer can sell a prescription drug, the Food and Drug Administration ("FDA") must approve it. 21 U.S.C. § 355(a). The FDA determines whether the drug is both effective and safe. 21 U.S.C. § 360c(a)(1)(C).

The process by which the FDA investigates the effectiveness and safety of a new drug begins when the manufacturer submits a "new drug application." The manufacturer submits "adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience."

[20] Information is primarily drawn from James M. Beck & Anthony Vale, Drug and Medical Device Product Liability Deskbook § 4.01 (ALM 2004). The undersigned also relies, in part, upon the "accumulated expertise" in learning about the FDA process for approving vaccines in many hearings.

21 U.S.C. § 355(d). These investigations occur through a series of clinical trials (commonly known as "phase I," "phase II," and "phase III"), in which the number of human participants expands. 21 C.F.R. § 312.21. Some drugs also undergo a "phase IV" or post-marketing trial.

The process of FDA approval includes a review of the drug's labeling. The FDA defines the content and format of labeling. 21 C.F.R. § 201.56. The label, in turn, must present information about contraindications, warnings and precautions, and adverse reactions. In the context of labels for prescription drugs, "an adverse reaction" is "an undesired effect, reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." 21 C.F.R. § 201.57(c)(7). The FDA distinguishes "adverse reactions" from "adverse events." The requirement to report "adverse reactions" is limited to "only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." Id.; see also 44 Fed. Reg. 37434, 37447 (June 29, 1979) (defining "reasonable evidence of association" as evidence "on the basis of which experts qualified by scientific training and experience can reasonably conclude that the hazard is associated with the drug").[21]

As part of the label's section on "adverse reactions," the manufacturer must distinguish between adverse reactions observed in clinical trials and adverse reactions gained in the post-marketing experience. 21 C.F.R. § 201.57(c)(7)(ii). After the FDA approves a prescription drug or biological product, a licensed manufacturer is required to report to the FDA any "adverse experience information." 21 C.F.R. § 600.80(c). The term "adverse experience" means "Any adverse event associated with the use of a biological product in humans, whether or not considered product related, including the following: An adverse event occurring in the course of the use of a biological product in professional practice." 21 C.F.R. § 600.80(a).

While manufacturers must report adverse experiences associated with its product to the FDA, "[a] report or information submitted by a licensed manufacturer . . . does not necessarily reflect a conclusion by the licensed manufacturer or FDA that the report or information constitutes an admission that

[21] The FDA's standard is not the same as the standard used in civil litigation because the FDA attempts to prevent the public from exposure to harmful substances. Glastetter v. Novartis Pharm. Corp., 252 F.3d 986, 991 (8th Cir. 2001) (applying Missouri law).

the biological product caused or contributed to an adverse effect." 21 C.F.R. § 600.80(*l*).

Manufacturers, however, are not the only entities that may report adverse events. Healthcare professionals and consumers may also report adverse events to the FDA. When healthcare professionals and consumers report adverse events to a manufacturer, the manufacturer is required to submit the report to the FDA. 21 C.F.R. § 600.80(c)(1)(iii).

3. Precedent regarding Product Inserts in the Vaccine Program

In different settings, judicial officers have discussed the value of FDA-required manufacturer's inserts and associated regulations.[22] Special masters have considered whether product inserts can support an expert's opinions that a vaccine can cause a condition.

Consequently, the cases discussed below do not match the exact circumstances of Ms. Cottingham's case in at least two respects. Here, the only evidence regarding the product insert is the product insert. There are no experts. No one has submitted testimony about the product insert. Second, Ms. Cottingham is attempting to establish the reasonable basis for the claim set forth in her petition. The evidentiary standard for reasonable basis is, as set forth above, lower than the preponderance of the evidence standard. Nevertheless, other judicial officials' considerations in evaluating the evidentiary value of product inserts are informative here to the extent that cases look at the post-marketing adverse events portion of product inserts.

The Secretary cites multiple cases supporting the conclusion that statements in package inserts do not constitute reliable evidence of causation and should not be considered admissions on the part of the manufacturers that a given product can or does cause a given injury. However, all but one of the cases cited by respondent ultimately rely on the statement in Werderitsh v. Secretary of Health & Human Services that "federal regulations specifically preclude the contents of drug product labels . . . from serving as admissions regarding causation." No. 99-319V, 2005 WL 3320041, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005).

[22] The Federal Circuit touched upon these regulations in the context of safe harbor provisions. See Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348, 1358 (Fed. Cir. 2012).

Werderitsh arose in a much different context. In that case, the petitioner sought to compel the production of VAERS files. Id. at *1. The petitioner contended, among other points, that the requested VAERS files underlie the entries in the Physician's Desk Reference. Id. at *8. (The Physician's Desk Reference, in turn, reproduces the FDA-approved product inserts. Id. at *8 n.22.) The petitioner apparently reasoned that the VAERS reports would shore up the "admissions" the government allegedly made in adopting the product insert. The special master rejected this argument because any information derived from VAERS reports would not constitute an admission from the government.

Although not expressly explained in Werderitsh, VAERS reports constitute a form of post-marketing experience. As a type of post-marketing information, the VAERS reports and any information communicated in the product insert based upon the VAERS reports would not constitute an admission that the vaccine caused an injury described in a VAERS report. 21 C.F.R. § 600.80. Werderitsh did not consider statements that appear in the product insert as a result of clinical trials.

The Secretary relies heavily on the statement in Sullivan v. Secretary of Health & Human Services that "[s]tatements contained in vaccine package inserts do not constitute reliable proof of causation, and cannot be deemed admissions that the vaccine in question has the capacity to harm a particular petitioner in a specific manner." No. 10-398V, 2015 WL 1404957, at *20 (Fed. Cl. Spec. Mstr. Feb. 13, 2015). This conclusion was derived directly from the preceding statement in Werderitsh but applied generally to "package inserts." The other cases cite to Sullivan and/or Werderitsh for this proposition. While some cases apply it to the general term "package inserts," encompassing clinical trial information and post-marketing reported events, see Carter v. Sec'y of Health & Human Servs., No. 16-852V, 2018 WL 6322447, at *8 n.10 (Fed. Cl. Spec. Mstr. Oct. 16, 2018); Rolshoven v. Sec'y of Health & Human Servs., No. 14-439V, 2018 WL 1124737, at *20 (Fed. Cl. Spec. Mstr. Jan. 11, 2018); Morris v. Sec'y of Health & Human Servs., No. 13-601V, 2017 WL 2461226, at *11 (Fed. Cl. Spec. Mstr. May 9, 2017), some apply the statement to post-marketing adverse events only, see Mondello v. Sec'y of Health & Human Servs., No 15-972V, 2018 WL 947449, at *11 (Fed. Cl. Spec. Mstr. Jan. 24, 2018) (applying the statement in a context involving *reported* adverse events); Bender v. Sec'y of Health & Human Servs., No. 11-693V, 2018 WL 3679637, at *1 (Fed. Cl. July 2, 2018) (applying the statement in the context of determining reliability of VAERS reports), mot. for rev. denied, 141 Fed. Cl. 262 (2019). None of these cases apply this statement of unreliability explicitly to clinical trials information contained in the product insert.

A nuanced analysis of the product insert would distinguish between, on the one hand, information provided in the sections for "contraindications," "warnings and precautions," and "adverse reactions" from clinical trials and, on the other hand, information provided in the post-marketing experience. The three former sections (sections 4, 5, and 6.1) comprise a notice from the vaccine manufacturer that some scientific basis supports a conclusion that the vaccine caused the listed problem. 21 C.F.R. § 201.57(c)(7). In contrast, the manufacturer's presentation of problems in the section on post-marketing experience (section 6.2) does not necessarily reflect a scientific basis.

4. Product Insert for HPV Vaccine

In this case, the more meaningful sections of the product insert provide a sliver of support for Ms. Cottingham's argument that the HPV vaccination harmed her. The product manufacturer warns that "Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended." Exhibit A at 3 (section 5.1). In clinical trials, some women reported having headaches within 15 days after the vaccination. Id. at 6.

The less valuable section of the product insert, the report on post-marketing experience, lists more than 20 conditions spread across nine categories. The category "nervous system disorders" includes "headache" and "syncope (including syncope associated with tonic-clonic movements and other seizure-like activity)." Exhibit A at 9-10.

The manufacturer's insert does not contain any information linking the HPV vaccine to menstrual difficulties. See Tr. 31. It also does not list the HPV vaccine as causing dysautonomia or autonomic dysfunction by name. See Tr. 32.

5. Events after the January 7, 2021 Fourth Fees Decision

In the parties' briefs associated with the fourth motion for review, the parties presented relatively few arguments about the package insert. See Pet'r's Br., filed Feb. 5, 2021; Resp't's Resp., filed Mar. 8, 2021; Pet'r's Reply, filed Mar. 15, 2021. The Court's opinion did not identify any specific errors in the undersigned's previous analysis of the package insert, but directed another examination of the package insert. Fourth Opinion, 2021 WL 3085502, at *8. In their most recent briefs, the parties essentially did not introduce any new arguments regarding the package insert.

After evaluation of the parties' briefs in conjunction with the fourth motion for review, the Court's July 7, 2021 Opinion, and the most recent briefs, the undersigned confirms the statements regarding the package insert. The package insert shows that syncope might develop within 15 minutes of vaccination and that headaches might develop within 15 days of vaccination. The package insert does not say anything about menstrual difficulties or dysautonomia by name.

V. Re-Assessment of Evidence Potentially Relevant to Reasonable Basis

Ms. Cottingham presented evidence, falling into three categories. First, she presented her medical records. While section I.A., above, discusses her medical records, they are again discussed in section A below to evaluate whether they support the claims contained in the petition. Second, section B below reviews her affidavit. Finally, an analysis of the medical articles is found in Section C.[23]

A. Medical Records

The Federal Circuit directed a more detailed analysis of certain medical records. Cottingham, 971 F.3d at 1346. Accordingly, the parties were directed to address them. Order, issued Oct. 15, 2020, ¶¶ 15-16. They are discussed in chronological order starting with the earliest created record. For reference, Ms. Cottingham received the allegedly causal vaccination on July 5, 2012.

November 30, 2012

Ms. Cottingham, who was 14 years old, saw a pediatrician, John Simpson. Ms. Cottingham reported that she was suffering from fever, yellow mucous, congestion, headaches "off and [on] all week," and a sore throat in the mornings. Exhibit 3 at 87-88 (appearing in the Joint Appendix at 35). When Dr. Simpson examined Ms. Cottingham, her nose and throat were "moderately congested and erythematous with some purulent postnasal discharge." Id. at 87. Dr. Simpson diagnosed Ms. Cottingham with cough, fever, and acute sinusitis. He prescribed Amoxil and discussed symptomatic care. Id. at 88; J.A. 35.

In treating Ms. Cottingham for congestion, headaches, and a sore throat, Dr. Simpson did not discuss the HPV vaccine. Dr. Simpson did not suggest that the HPV vaccine caused any of these symptoms.

[23] A fourth type of evidence, the product insert, was just discussed.

January 31, 2013

Ms. Cottingham returned to the pediatrician's group and saw a different pediatrician, Elizabeth Crum. The complaints were that Ms. Cottingham suffered from runny nose and congestion for two days, a low-grade fever, a sore throat, and a headache "today." Exhibit 3 at 78. Ms. Cottingham was not having a cough, shortness of breath, vomiting, or diarrhea. Id. Dr. Crum diagnosed Ms. Cottingham with rhinitis and acute viral pharyngitis. Id. at 79. Dr. Crum prescribed a course of Zyrtec and planned for symptomatic care. Id.; J.A. 61.

Dr. Crum did not mention the HPV vaccination in the note for the appointment for Ms. Cottingham's runny nose, congestion, fever, sore throat, and headache. Dr. Crum did not indicate that the HPV vaccination caused any of these symptoms.

March 29, 2013

Ms. Cottingham acutely experienced "fever and dizziness" the morning of this appointment. Exhibit 3 at 80. She stated that she fainted that morning. She also stated that she vomited once but had no diarrhea. Id. A urinalysis showed "very slight dehydration." Id. The doctor who examined Ms. Cottingham, Richard Stone, diagnosed her with gastroenteritis and dehydration. He indicated that Ms. Cottingham was "at the early stage of an intestinal virus." Id. at 81; J.A. 62.

Dr. Stone did not say anything about the HPV vaccination. Dr. Stone did not opine that the HPV vaccination contributed to Ms. Cottingham's fainting or dehydration.

May 23, 2013

Ms. Cottingham informed Dr. Crum that she did not eat or drink anything when she woke up. She and a friend went to lay out at a pool. She felt hot. When she got up quickly to get something to eat, her vision became black and she felt lightheaded. Her friend witnessed her fall backwards and hit her head on the ground. The history noted that Ms. Cottingham had a similar episode in March 2013. Ms. Cottingham "does not have a history of syncope with exercise." Exhibit 3 at 70. Dr. Crum examined her and found a "[c]ompletely normal neurologic exam. . . . Five out of five motor strength in all extremities." Id. at 71. Dr. Crum tested Ms. Cottingham's orthostatic blood pressure and it remained stable. But, Ms. Cottingham's "heart rate did increase from 80 to 100 when going from laying to standing." Id. Dr. Crum determined that Ms. Cottingham was dehydrated and assessed her with fainting. Dr. Crum recommended that Ms.

Cottingham increase her intake of fluids and eat breakfast. Dr. Crum commented, "if these events continue to occur I would consider further evaluation at that time, but do feel like [these] are likely two isolated events related to dehydration." Id.; J.A. 63-64.

At this appointment for another episode of fainting, Dr. Crum did not mention the HPV vaccination. Dr. Crum did not suggest that the HPV vaccination contributed to Ms. Cottingham's episodes of fainting.

July 25, 2013

Upon a referral from Dr. Simpson, Ms. Cottingham saw a pediatric cardiologist, Waldemar Carlo. Ms. Cottingham told Dr. Carlo that she "had several episodes of dizziness and passing out" beginning in March. Exhibit 3 at 111. With all the episodes, Ms. Cottingham "is standing or walking." "She has not had any dizziness or syncope with physical activity." Id. Dr. Carlo performed an electrocardiogram and echocardiogram. After testing, he determined that Ms. Cottingham's heart was structurally normal and functioning normally. Dr. Carlo diagnosed her with vasovagal syncope and urged Ms. Cottingham to hydrate aggressively. Id. at 112. Dr. Carlo specifically declined to schedule a follow-up appointment but noted he would see her again if any new signs or symptoms developed. Id.; J.A. 36, 65.

Dr. Carlo did not discuss the HPV vaccination in his note for this appointment about dizziness and passing out. Dr. Carlo did not say that the HPV vaccination might have caused Ms. Cottingham's problems.

May 14, 2015

Ms. Cottingham's mother called the pediatrician's office to report that her daughter had not had a menstrual cycle in six months. Ms. Cottingham's mother also stated that "the Gardasil series may have something to do with the recent changes noted in [her daughter's] menstrual cycle." Exhibit 3 at 175. The nurse advised Ms. Cottingham's mother that "a note will be made." Id.; J.A. 60.

The medical record does not contain any response from a physician. No record indicates that the pediatrician who received the note about the concern of Ms. Cottingham's mother thought that the HPV vaccination may have caused changes in Ms. Cottingham's menstrual cycle.

Assessment

The Secretary argues that Ms. Cottingham's "medical records indicate that *none* of her treating physicians implicated the Gardasil vaccine as contributing to petitioner's various complaints *in any way*." Resp't's Br., filed Nov. 19, 2020, at 7. This assessment appears accurate.

Ms. Cottingham relies upon passages from the Federal Circuit. See Pet'r's Br., filed Nov. 19, 2020, at 15. "Here, the record contains seven medical-examination reports detailing [Ms. Cottingham's] medical history that address injuries she suffered. The Gardasil package insert links [her] injuries to adverse reactions associated with Gardasil's administration." Cottingham, 917 F.3d at 1346. Ms. Cottingham argues that these medical records "identify the exact conditions alleged to have been triggered by the vaccination at issue. They are the exact conditions reflected in the Gardasil product monograph, and they are the exact conditions documented in the cited medical literature as constituting post-Gardasil adverse events." Pet'r's Br. at 15.[24]

Because the treating doctors did not link any condition in Ms. Cottingham to the HPV vaccination, the undersigned earlier stated that Ms. Cottingham produced "no evidence" supporting causation. Third Decision, 2018 WL 3432638, at *5; accord Resp't's Resp., filed Nov. 14, 2016, at 4; Resp't's Mot. for Rev., filed Jan. 10, 2018, at 14. However, on appeal, the Federal Circuit held that the "no evidence" determination "rests on a clearly erroneous fact finding." Cottingham, 971 F.3d at 1345.

In light of the Federal Circuit's vacatur and remand, the undersigned has examined the medical records the Federal Circuit identified and looked to the totality of the circumstances in evaluating the weight of this evidence to the question of reasonable basis. These records show that at some time (in some instances many many months) after the vaccination, Ms. Cottingham experienced health problems. Thus, the sequence of events in which the vaccination preceded the onset of the headaches, fainting, and menstrual problems makes it logically possible for Ms. Cottingham to assert that the vaccination caused the headaches, fainting, and menstrual problems. By way of contrast, if Ms. Cottingham had experienced a pattern of headaches, fainting, and menstrual problems before the

[24] Ms. Cottingham's assertion that the medical records document conditions "reflected in the Gardasil product monograph" is partially correct. As discussed above, the product insert does not discuss menstrual difficulties or dysautonomia.

vaccination, then she could not logically allege that the vaccination caused those problems. Locane v. Sec'y of Health & Human Servs., 685 F.3d 1375, 1380-81 (Fed. Cir. 2012). Under the guidance from the Federal Circuit, the undersigned recognizes that the medical records showing Ms. Cottingham suffered maladies after the vaccination constitute some evidence that is consistent with a finding of causation.

In the context of determining whether petitioners are entitled to compensation in which special masters look for preponderant evidence, numerous cases have stated that a sequence of events in which the vaccination came before the onset of the injury does not establish the causal relationship. The Federal Circuit articulated this principle in one of the earliest cases from the Vaccine Program at the Federal Circuit. Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992).

While Grant resolved questions of entitlement, the same evidence of a sequence of events in which the vaccination preceded the onset of a disease or disorder was determined not to confer reasonable basis by itself. "Temporal proximity is necessary, but not sufficient." Chuisano v. United States, 116 Fed. Cl. 276, 287 (2014).[25] "[T]o establish a reasonable basis for the claim, petitioner was obliged to adduce medical evidence going to causation beyond temporal proximity." Bekiaris v. Sec'y of Health & Human Servs., 140 Fed. Cl. 108, 115 (2018).

[25] To some extent, the reasoning in Chuisano (that timing is necessary but not sufficient) is inconsistent with the reasoning in Harding v. Sec'y of Health & Human Servs., 146 Fed. Cl. 381 (2019). Ms. Harding was suffering from a disease known as Wegener's granulomatosis (also known as granulomatosis polyangiitis) when she received doses of the HPV vaccine in October and November 2014. 146 Fed. Cl. at 387-88. Within approximately three weeks of the November 2014 dose, Ms. Harding's condition was worse. Id. at 388. Ms. Harding alleged that the vaccinations significantly aggravated her pre-existing disease, but eventually filed a motion to dismiss her case voluntarily without filing an expert report.

The special master found that Ms. Harding satisfied the reasonable basis standard because, in part, "'the medical records document[ed] a flare of an autoimmune disease shortly after administration of a covered vaccine.'" Id. at 392 (quoting Harding v. Sec'y of Health & Human Servs., No. 17-1580V, 2019 WL 3215974, at *7 (Fed. Cl. Spec. Mstr. June 18, 2019)). The Court of Federal Claims ruled that the special master (1) considered the relevant evidence, (2) drew plausible inferences, and (3) stated a rational basis for the outcome and, accordingly, denied the Secretary's motion for review. Id. at 404.

B. Affidavits

In addition to providing medical records created contemporaneously with some events described in the medical records, Ms. Cottingham also submitted an affidavit she signed on October 28, 2015. Exhibit 1 at 3. In some ways, Ms. Cottingham's testimony is consistent with information contained in the medical records. For example, Ms. Cottingham avers that she received a dose of the HPV vaccination on July 5, 2012. Id. ¶ 3.

After the Federal Circuit's opinion ordering a remand in Cottingham, the next Federal Circuit's opinion clarified the value of affidavits in the context of determining reasonable basis. The Federal Circuit stated: "Medical records related to [] symptoms would likely be based on the statements of those who experienced them. And while such medical records may indeed serve as important corroborating evidence for evaluating testimony's credibility, we reject the Special Master's broad pronouncement that petitioners' affidavits are categorically 'not "objective" for the purposes of evaluating reasonable basis.'" James-Cornelius, 984 F.3d at 1380.

In accord with James-Cornelius, the undersigned has reassessed the value of Kaci Cottingham's affidavit. Ms. Cottingham's affidavit provides a scintilla of support that in November 2012, she "began to experience episodes of near black-outs." Exhibit 1 ¶ 5.

However, Ms. Cottingham's statement regarding an onset of near black-outs in November 2012 is worth, in the undersigned's experience, no more than a scintilla. See Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1104 (Fed. Cir. 1996) (noting that special masters may use their accumulated expertise in evaluating cases). Although Ms. Cottingham is competent to assert when she experienced health problems, Kirby v. Sec'y of Health & Human Servs., 997 F.3d 1378 (Fed. Cir. 2021), Ms. Cottingham's assertions do not have to be accepted at face value automatically.

When considered as a whole, see 42 U.S.C. § 300aa–13(a), the record suggests that Ms. Cottingham's assertion that she began to experience near black outs in November 2012 is highly implausible. See Order Denying Reconsideration, 2017 WL 2209904, at *4 (indicating that in 2017 the undersigned found Ms. Cottingham's affidavit "strain[ed] credibility"). It seems likely that if a 14-year-old young woman nearly blacked out repeatedly, she would be likely to tell (a) her parents, (b) a medical professional, such as a doctor or school nurse, or (c) her parents and medical professionals. Parents, in turn, are likely to be attentive

to a potentially serious health concern as Ms. Cottingham's mother did after Ms. Cottingham fainted twice. In the July 10, 2013 medical appointment with Dr. Simpson, Ms. Cottingham's mother requested an echocardiogram. Exhibit 3 at 96.

Upon learning that an otherwise healthy adolescent was nearly blacking out, a medical professional would, in the undersigned's experience, document that report and investigate it. For example, when Ms. Cottingham first informed a doctor about blacking out on May 23, 2013, Dr. Crum determined that it was likely due to dehydration but cautioned that if the episodes repeated, she should seek additional medical attention. Exhibit 3 at 70.

The history that Dr. Crum obtained suggests that medical professionals investigate reports of blacking out thoroughly. Dr. Crum recorded that Ms. Cottingham reported a prior episode in March 2013. Exhibit 3 at 70. This history does not say that Ms. Cottingham has had prior episodes of near black outs going back six months to November 2012. It seems likely that if Ms. Cottingham continued to have near black outs for multiple months as her affidavit asserts, exhibit 1 ¶ 7, then she would have communicated this information to Dr. Crum.

Likewise, Dr. Simpson memorialized that Ms. Cottingham "has had two syncopal spells, one in March 2013 and a second in May 2013." Exhibit 3 at 96. Considering that one purpose of the visit with Dr. Simpson on July 10, 2013 was to evaluate these fainting episodes, it seems likely that Dr. Simpson would have asked how often Ms. Cottingham had episodes of dizziness, nearly passing out, or fainting. Dr. Simpson's notation that Ms. Cottingham had "two syncopal spells" constitutes evidence that she did not have three. If Ms. Cottingham did have more episodes of fainting (or nearly fainting) as she asserted in her affidavit, then she would have told Dr. Simpson.

It seems rather much more likely that Ms. Cottingham's memory about when she experienced near black outs is inaccurate. After all, her October 28, 2015 affidavit was prepared approximately three years after the asserted onset of near black outs (November 2012). Multiple judicial opinions have recognized the commonly known fact that memories fade over time.[26] See Reusser v. Sec'y of

[26] To be sure, if the case had proceeded, Ms. Cottingham, her mother, the pediatrician who created medical records about Ms. Cottingham on November 30, 2012 (Dr. John Simpson), and Dr. Crum might have testified at a hearing. During this hearing, Mr. Downing may have impeached the doctor's ability to create accurate medical records, leading to a finding that Ms. Cottingham's 2015 affidavit about the onset of her near black outs was more accurate than medical records created in 2012 and 2013. But, this outcome was not likely.

Health & Human Servs., 28 Fed. Cl. 516, 523 (1993) (stating that "written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit years later"); Sullivan v. Sec'y of Health & Human Servs., No. 10-398V, 2013 WL 4011056, at *10-11, 14 (Fed. Cl. Spec. Mstr. June 30, 2013) (crediting medical records over affidavit testimony in part because of the faultiness of memory in recollecting specific events); Thomas v. Sec'y of Health & Human Servs., No. 01-645V, 2007 WL 470410, at *15 (Fed. Cl. Spec. Mstr. Jan. 23, 2007) (stating that the Court may find statements unreliable where "recollections are imprecise as to the specific timing of particular events").

C. Medical Articles

"Medical articles," in this context differ from the product insert. As explained above, the Secretary filed the product insert as exhibit A, and the product insert, accordingly, was in the record before the Federal Circuit. But, Ms. Cottingham only cited various articles and did not file them into the record before the appeal to the Federal Circuit. Thus, the Federal Circuit did not explicitly direct a consideration of these articles in its Order.

After the remand, Ms. Cottingham filed five articles, discussed below. The Secretary acquiesced to their inclusion by not filing a motion to strike. See Resp't's Br., filed Nov. 19, 2020, at 12. Accordingly, the parties were directed to address the articles. Order, issued Oct. 15, 2020, ¶¶ 8-9.

Ms. Cottingham refers to her June 2, 2017 reply in support of her first motion for review, which is CM/ECF entry 53. Pet'r's Br., filed Aug. 9, 2021, at 9. In that reply, Ms. Cottingham argued that the Martinez-Lavin, Kinoshita, and Brinth articles connected the human papillomavirus vaccine to autonomic dysfunction. She maintains that position in her November 19, 2020 brief, asserting that "Autonomic dysfunction (dysautonomia) has been connected to vaccination, particularly Gardasil." Id.. In the December 14, 2020 oral argument, Ms. Cottingham explained that she offered the articles for the limited purpose of showing that her claim is "not novel." Tr. 37. She has presented, in her words, "a bunch of case reports" that resemble her situation. Id. at 38. Ms. Cottingham maintains that the similarities between the facts of her case and the reports in articles she cited bolsters her contention that a reasonable basis supports the claims set forth in her petition.

The Secretary makes multiple arguments against the value of the articles. Resp't's Br, filed Nov. 19, 2020, at 12-13. One argument is that four articles

discuss conditions with which Ms. Cottingham was not diagnosed. Id. at 13. The Secretary maintained that "There is no evidence in the medical records of [Ms. Cottingham] being diagnosed with autonomic dysfunction." Id. at 7. Another general argument is that the articles need to be tied to the facts of Ms. Cottingham's case. Tr. 38-39.

Review of Articles

To address the value of the five medical articles Ms. Cottingham submitted, each is reviewed below. The sequence begins with the earliest published article.

S. **Blitshteyn** reported "six previously healthy young women [who] developed symptoms of POTS [postural orthostatic tachycardia syndrome] within 6 days to 2 months after immunization with Gardasil vaccine." S. Blitshteyn, *Postural tachycardia syndrome following human papillomavirus vaccination*, 21 Euro. J. Neuro. 135 (2014), filed as exhibit 14, at 138. In addition to being diagnosed with POTS, three of the patients also had neurocardiogenic syncope. Id. Dr. Blitshteyn concluded "Further studies are necessary to investigate whether there is a causal relationship." Id. at 139.[27]

The Blitshteyn article describes patients as suffering headaches and neurocardiogenic syncope after HPV vaccination. According to Ms. Cottingham, it offers some support for the reasonable basis of her claim that the HPV vaccination caused her to suffer headaches and fainting. Tr. 42. However, with regard to headaches and fainting, the subjects in the Blitshteyn article experienced those problems much closer in time to the vaccination than Ms. Cottingham. See exhibit 14 at 136 (table 1 listing onset of various problems between two weeks and two months after the vaccination). The Blitshteyn article does not help with Ms. Cottingham's claim for menstrual problems and dysautonomia. Tr. 46.

Kinoshita and colleagues observed that over the course of approximately nine months, they treated 40 girls, who complained that they had symptoms after receiving a vaccination against human papillomavirus. (About one-quarter of this

[27] Dr. Blitshteyn has participated in Vaccine Program proceedings as an expert witness. See McCulloch v. Sec'y of Health & Human Servs., No. 09-293V, 2015 WL 3650610 (Fed. Cl. Spec. Mstr. May 22, 2015) (finding petitioner was entitled to compensation); Turkupolis v. Sec'y of Health & Human Servs., No. 10-351V, 2014 WL 2872215, at *21 (Fed. Cl. Spec. Mstr. May 30, 2014) (denying compensation and stating "Dr. Blitshteyn proffers her conclusion and then speculates it must be because it happens to other people with diseases that petitioner does not have. Speculation is unacceptable as credible proof.").

population received the same brand, Gardasil, as Ms. Cottingham received.) The average age of this population was 13.7 years. Tomomi Kinoshita et al., *Peripheral Sympathetic Nerve Dysfunction in Adolescent Japanese Girls Following Immunization with the Human Papillomavirus Vaccine*, 53 Internal Medicine 2185 (2014), filed as exhibit 13, at 2.

These patients reported various symptoms. The most common symptom was headaches, followed by general fatigue. Orthostatic fainting and disturbed menstruation were also reported. Id. "The average incubation period after the first dose of vaccine was 5.47±5.00 months." Id. Kinoshita and colleagues diagnosed most of the young girls as suffering from chronic regional pain syndrome and/or orthostatic problems. Id. at 10; see also id. at 13 (table 5).

With respect to etiology, "[b]ased on the temporal relationship between immunization and the development of symptoms, [the authors] cannot deny the possibility that immunization with HPV vaccines may secondarily induce sympathetically mediated disorders, including CRPS-I [chronic regional pain syndrome], OH [orthostatic hypotension] and POTS [postural tachycardia syndrome]." Id. at 15. They concluded: "Studies with large-scale investigations and experimental approaches are needed to further answer these questions." Id.

Ms. Cottingham downplayed the diagnoses given to the patients in the Kinoshita article, calling them "labels." Tr. 49. Ms. Cottingham viewed the symptoms that Kinoshita and colleagues reported as more germane to her argument. Accordingly, Ms. Cottingham pointed out that more than half the population in the Kinoshita review reported headaches. Tr. 48. Ms. Cottingham also emphasized that the average temporal interval "5.47 months" was "peg[ged]" to her case. Tr. 52, 85.

Blitshteyn and Kinoshita were included in the introductory section of **Brinth**. Louise S. Brinth et al., *Orthostatic intolerance and postural tachycardia syndrome as suspected adverse effects of vaccination against human papillomavirus*, 33 Vaccine 2602 (2015), filed as exhibit 12, at 2602. The Brinth team evaluated 35 patients who had been referred to their syncope unit for further evaluation for "a suspected adverse event following vaccination with the quadrivalent HPV vaccine." Id. The 35 females had an average age of 23.3 years. "The mean delay between vaccination and onset of symptoms was 9.3 days (range: 0–30)." Id. "Mean time between onset of symptoms and examination was 1.9 years (range: 0–5)." Id. After testing, the researchers determined that 60 percent of the group suffered from POTS. Id. at 2604. The authors proposed their group

might "possibly constitut[e] a post vaccination syndrome on an autoimmune basis in a specific group of young women." Id.

Brinth and colleagues acknowledged three limitations to their study. The first was a "lack of a control group." Id. The second was "the long and variable delay between the onset of symptoms and orthostatic testing." Id. The third was the use of a ten-minute tilt-table test might miss other forms of chronic orthostatic intolerance. The authors concluded that: "Our findings do not confirm or dismiss a causal link to the HPV-vaccine—but suggest that further research is urgently warranted." Id.

Ms. Cottingham argued that like the Kinoshita article, the Brinth article supported Ms. Cottingham's presentation of symptoms. Tr. 51. However, Ms. Cottingham acknowledged that average latency between vaccination and the onset of symptoms in Brinth (9.3 days) was much different from the average reported in Kinoshita and much different from her experience. Tr. 52.

The next article, **Martinez-Lavin**, starts with observations from Blitshteyn, Kinoshita, and Brinth, as well as others. The Martinez-Lavin article proposed "as a hypothesis that small fiber neuropathy may also explain the pain and autonomic dysfunction seen in post HPV vaccination syndrome." Manuel Martinez-Lavin, *Hypothesis: Human papillomavirus vaccination syndrome—small fiber neuropathy and dysautonomia could be its underlying pathogenesis*, 34 Clin. Rheumatol. 1165 (2015), filed as exhibit 11, at 3. In oral argument, Ms. Cottingham recognized that she was not diagnosed as suffering from small fiber neuropathy. Tr. 54. This concession reduces the value of the Martinez-Lavin article.

The most recently published article is by **Kazuki Ozawa** and colleagues. Kazuki Ozawa et al., *Suspected Adverse Effects After Human Papillomavirus Vaccination: A Temporal Relationship Between Vaccine Administration and the Appearance of Symptoms in Japan*, 40 Drug Saf. 1219 (2017), filed as exhibit 15. These researchers built upon their earlier report, Kinoshita, which is reference 10 in Ozawa. The purpose of Ozawa's work was "to clarify the temporal relationship between human papillomavirus vaccination and the appearance of post-vaccination symptoms." Id. at 1. For this study, Ozawa and group created a set of diagnostic criteria. However, the validity and reliability of the newly created diagnostic criteria "have not been established." Id.

In oral argument, when asked whether Ozawa constituted "reliable" evidence pursuant to Vaccine Rule 8(b)(1), Ms. Cottingham maintained that Ozawa was reliable "for the purpose for which this article is being offered." Tr.

55. The purpose of the article, in turn, is that Ozawa "details the syndrome of symptoms that you may see following" the HPV vaccine. Tr. 56. The Secretary asserted that the Ozawa article cannot be relied upon. Tr. 60.

Using their diagnostic criteria, Ozawa and colleagues diagnosed 30 patients with "definite vaccine-related symptoms" and another 42 patients with "probable" vaccine-related symptoms. Exhibit 15 at 1. This group of 72 patients came from a starting group of 163 patients. Id. The average age at vaccination for these 72 patients was 13.6 years. "The time to onset after the first vaccine dose ranged from 1 to 1532 days (average 319.7 ± 349.3 days)." Id.

The researchers asked the participants to answer questionnaires, obtained medical records from other facilities when available, and conducted tests on the participants. Id. at 3. "Symptoms or signs frequently observed in these 72 girls were prolonged general fatigue, chronic headache, widespread pain, limb shaking, dysautonomic symptoms, motor dysfunction, abnormal sensation, sleep disturbance, learning impairment, and menstrual abnormality." Id. at 5. "Dysautonomic symptoms included frequent squatting or syncope during their daily activities." Id.

The Ozawa researchers recognized some limitations in their study. These included not having a control group and having a relatively small number of subjects, all of whom were referred to the authors. Id. at 9. The authors stated that "HPV vaccination is temporally related to the development of these symptoms in Japanese adolescent girls. Further large-scale studies are required to clarify the pathophysiology of these symptoms." Id. at 9.

Ms. Cottingham offered the Ozawa article for the limited purpose of showing that her report of symptoms after receiving the HPV vaccine was typical. Tr. 55-56. Ms. Cottingham explicitly disclaimed any reliance on Ozawa's report of temporality, which extended from 1 to 1532 days. Tr. 62. As the Secretary pointed out, 1532 days is more than 4 years after vaccination. Tr. 60. Ms. Cottingham's attorney acknowledged that he would not endorse a claim that the HPV vaccination caused an injury appearing "3 years" after vaccination. Tr. 53. However, the attorney was not asked to reconcile this position with the information in the Ozawa article.

Cases Evaluating these Articles

The "accumulated expertise" on which special masters may rely in deciding cases, see Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1104

(Fed. Cir. 1996), includes an awareness of how issues have been resolved previously. These previous dispositions are not binding. Boatmon v. Sec'y of Health & Human Servs., 941 F.3d 1351, 1358-59 (Fed. Cir. 2019). But the non-binding value of those informed considerations should not negate their value, especially when the parties have not presented any testimony from an expert about the articles.[28]

In general, special masters have found this set of articles not sufficiently persuasive to assist any petitioners in meeting their burden to show, by a preponderance of the evidence, the HPV vaccine can cause different injuries. A thorough analysis appears in Balasco v. Secretary of Health & Human Services, No. 17-215V, 2020 WL 1240917 (Fed. Cl. Spec. Mstr. Feb. 14, 2020). Represented by Mr. Downing, Julia Balasco alleged that the HPV vaccine caused her to suffer "autonomic dysfunction, postural orthostatic tachycardia syndrome (POTS), fibromyalgia, and orthostatic intolerance (OI)." Id. at *1. To advance her claim, Ms. Balasco submitted reports from Yehuda Shoenfeld and Mitchell Miglis. Id. at *2. (Dr. Shoenfeld and Dr. Miglis have testified for petitioners in other cases as well.) The Secretary opposed the claim and offered contrary reports.

After considering the five articles discussed above as well as additional evidence, the special master did not find "preponderant evidence of any HPV Syndrome or that the above-discussed literature, considered individually or as a whole, provides a basis for [Ms. Balasco] to assert a claim for an adverse reaction to her HPV vaccine." Id. at *32. In addition, the special master rejected Ms. Balasco's argument that she satisfied the Ozawa criteria. Id. at *29.

In Johnson v. Secretary of Health & Human Services, No. 14-254V, 2018 WL 2051760 (Fed. Cl. Spec. Mstr. Mar. 23, 2018), the special master reached a similar conclusion. In Johnson, the special master heard testimony from Dr. Shoenfeld and Kenneth Mack, a doctor the Secretary had retained, regarding Ms. Johnson's claim that she suffered a variety of injuries, including POTS. In reference to the Blitshteyn, Brinth, Kinoshita, and Ozawa articles, the special master found that "Dr. Mack convincingly explained in particular why many of the items of literature that relied on such case study data were untrustworthy—the studied subjects voluntarily had sought treatment for their orthostatic symptoms,

[28] The special masters had not decided cases like Balasco until after Ms. Cottingham had filed and dismissed her petition. On the other hand, Ms. Cottingham did not file the articles into this case until October 13, 2020. CM/ECF No. 86.

making the studied group too self-selected to draw conclusions from correlations observed with respect to that population." Id. at *24.

Other cases have refrained from crediting the articles Ms. Cottingham advances, though with less robust analyses. See Yalacki v. Sec'y of Health & Human Servs., No. 14-278V, 2019 WL 1061429, at *14 n.21 (Fed. Cl. Spec. Mstr. Jan. 31, 2019) (mentioning Dr. Shoenfeld's reliance on the Martinez-Lavin article despite the petitioner's lack of small fiber neuropathy); Combs v. Sec'y of Health & Human Servs., No. 14-878V, 2018 WL 1581672, at *18 (Fed. Cl. Spec. Mstr. Feb. 15, 2018) (finding the Kinoshita article not persuasive because it involved "a very limited number of case studies"). The undersigned identified only one case in which this set of articles was filed and the petitioner was found entitled to compensation. But, in that case, the petitioner's expert disclaimed any reliance on an autonomic injury. See B.A. v. Sec'y of Health & Human Servs., No. 11-51V, 2018 WL 6985218, at *27-29 (Fed. Cl. Spec. Mstr. Dec. 6, 2018) (finding petitioner established that the HPV vaccination caused her headaches via molecular mimicry).

Balasco and Johnson point out that essentially, the Blitshteyn, Brinth, Kinoshita, and Ozawa articles present a series of case reports. Although the articles, particularly the Ozawa article, discuss findings on more than an isolated case, the articles all suffer from a lack of control group. Case reports provide little, if any, value to an analysis of causation. See Porter v. Sec'y of Health & Human Servs., No. 99-639V, 2008 WL 4483740, at *13 (Fed. Cl. Spec. Mstr. Oct. 2, 2008), set aside on other grounds by Rotoli v. Sec'y of Health & Human Servs., 89 Fed. Cl. 71 (2009), reinstated, 663 F.3d 1242, 1254 (Fed. Cir. 2012) (stating the "special master's decision reveals a thorough and careful evaluation of all of the evidence, including . . . reports and medical literature"); W.C. v. Sec'y of Health & Human Servs., No. 07-456V, 2011 WL 4537887, at *13 (Fed. Cl. Spec. Mstr. Feb. 22, 2011) ("[C]ase reports are generally weak evidence of causation because [they] cannot distinguish a temporal relationship from causal relationship."), mot. for rev. denied, 100 Fed. Cl. 440 (2011), aff'd, 704 F.3d 1352 (Fed. Cir. 2013). Given the methodological limitations that are contained within the text of the articles, the undersigned cannot give these articles more than a trifle of weight.

But, even the very small value of these articles diminishes in the context of Ms. Cottingham's claim. As the Secretary argues, see Resp't's Br. at 12-13, Ms. Cottingham does not suffer from the conditions primarily discussed in those articles. Blitshteyn investigated six young women who suffered from POTS. Exhibit 14 at 138. Orthostatic problems and chronic regional pain syndrome were the primary diagnoses in Kinoshita. Exhibit 13 at 10. In Brinth, 60 percent of the

subjects suffered from POTS. Exhibit 12 at 2604. Martinez-Lavin proposed that autonomic dysfunction was explained by small fiber neuropathy. Exhibit 11 at 3. However, Ms. Cottingham has not presented any evidence that she suffers from POTS, chronic regional pain syndrome, orthostatic problems, or small fiber neuropathy. Ms. Cottingham has also not presented any evidence (as opposed to attorney argument) for why, for example, an article about chronic regional pain syndrome informs an analysis of the reasonable basis for a claim that a vaccination caused her to suffer, for example, syncope.[29]

VI. Assessment of Whether Reasonable Basis Supports the Claims Set forth in the Petition

Having evaluated the evidence Ms. Cottingham and the Secretary submitted as the Federal Circuit directed and the additional topics the Court of Federal Claims identified, the undersigned next turns to determining whether, based on the totality of the circumstances, Ms. Cottingham supported the claims set forth in her petition. The structure of this analysis borrows from the structure used in off-Table cases to determine whether a petitioner is entitled to compensation. However, and this qualification is important, the burden of proof for determining whether a petitioner establishes a reasonable basis for the claims set forth in the petition is lower than the burden of proof to establish entitlement to compensation. Petitioners can more easily satisfy the reasonable basis standard than the preponderance of the evidence standard.

Ms. Cottingham's October 30, 2015 petition asserted that the HPV vaccination caused her four different problems. The easiest to evaluate is the claim that the HPV vaccination caused Ms. Cottingham to suffer dysautonomia. Thus, that condition is evaluated first in section A below. The remaining three conditions are evaluated on the basis by which Ms. Cottingham began to

[29] Conceivably, an expert might be able to connect the dots. However, speculating about what could have happened would violate the requirement in Simmons to evaluate objective evidence.

When an expert has offered an opinion that an HPV vaccine harmed a petitioner based upon these articles, special masters have found that the petitioners were entitled to attorneys' fees and costs. See Pet'r's Reply in Support of Fourth Mot. for Rev., filed March 15, 2021, at 7, citing Balasco v. Sec'y of Health & Human Servs., No. 17-215V, 2020 WL 2461911 (Fed. Cl. Spec. Mstr. Apr. 16, 2020) and Combs v. Sec'y of Health & Human Servs., No. 14-878V, 2018 WL 2772218 (Fed. Cl. Spec. Mstr. Apr. 23, 2018). The outcomes in those cases can be reconciled to the outcome in this case because in Balasco and Combs, the petitioners made a stronger evidentiary showing.

experience the condition, starting with the earliest. The claim that the HPV vaccination caused Ms. Cottingham to have headaches is in section B below. The claim regarding fainting is in section C below. The claim regarding menstrual difficulties is in section D below.

A. **Dysautonomia**

The petition asserts "[Ms. Cottingham]'s mom decided that she did not want [her] to have any further Gardasil shots due to a potential connection with autonomic dysfunction, and declined them at [her] July 7, 2013 annual physical." Pet. ¶ 8. The citation for this assertion is Ms. Cottingham's affidavit, exhibit 1.

Ms. Cottingham's annual physical was actually July 10, 2013. Exhibit 3 at 96-98. During this appointment, Dr. Simpson (a pediatrician) discussed the two episodes of fainting and recommended that she eat breakfast and drink regularly. He also referred Ms. Cottingham to a pediatric cardiologist. The records from this appointment do not refer to Ms. Cottingham as possibly suffering from autonomic dysfunction. Id. Likewise, Ms. Cottingham's affidavit to which the petition refers does not use the term "autonomic dysfunction," although the affidavit otherwise discusses a July 7, 2013 physical examination. See exhibit 1 ¶ 14.

The October 15, 2020 order directed Ms. Cottingham to specify the claims for which the petition was brought and to identify the evidence showing that Ms. Cottingham suffered from those conditions. Order, issued Oct. 15, 2020, ¶¶ 5-6. In response, Ms. Cottingham stated that the "'claim for which the petition was brought' includes autonomic dysfunction manifesting as headaches, lightheadedness described as near black-outs, syncope, and menstrual problems." Pet'r's Br. at 6. She continued: "These can constitute separate conditions or well-documented symptoms of her overarching condition of autonomic dysfunction." Id. In oral argument, Ms. Cottingham's attorney, Mr. Downing, amplified his perspective about Ms. Cottingham's diagnosis. Mr. Downing stated: "I do think that she has dysautonomia." Tr. 47. The Ozawa article attempts "to define the syndrome by a collection of symptom sets in the body systems that appear to be disconnected, but they're not." Tr. 56; accord Tr. 138.

In contrast, the Secretary responded: "There is no evidence in the medical records of petitioner being diagnosed with autonomic dysfunction." Resp't's Br. at 7. The Secretary rejected Mr. Downing's attempt to diagnose Ms. Cottingham as suffering from dysautonomia or a syndrome because doctors who treated her are "the more reliable source for what is going on with Ms. Cottingham." Tr. 77.

Establishing that the vaccinee suffers from the condition a vaccination allegedly caused is a fundamental aspect of a claim. Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010).

Here, even under a standard of proof that is less than the preponderance of the evidence standard, Ms. Cottingham has not presented a reasonable basis for the petition's claim that she suffered "autonomic dysfunction."[30] The crucial point is that Ms. Cottingham presented no evidence in which a doctor diagnosed her as suffering from "autonomic dysfunction." Even the petition states that Ms. Cottingham's *mother* was concerned about "a potential connection with autonomic dysfunction." Pet. ¶ 8. The petition does not elaborate on the basis for Ms. Cottingham's mother's concern.

The belief of Ms. Cottingham's mother, regardless of its foundation, seems to be a subjective quality that falls into the category of "good faith." By way of contrast, Ms. Cottingham's mother's worry about "autonomic dysfunction" is not a form of "objective evidence" on which decisions about reasonable basis turn. Ms. Cottingham's attorney points to headaches in the context of a diagnosed viral infection approximately four months after vaccination, two episodes of fainting reported in the medical records in the context of being dehydrated and not eating approximately eight and ten months after vaccination, and menstrual difficulties beginning five months after the second vaccination, as evidence of a sequence of symptoms amounting to autonomic dysfunction. However, the perception of Ms. Cottingham's attorney that the series of symptoms Ms. Cottingham experienced actually constitute a syndrome is also not grounded in sufficient objective evidence to have a reasonable basis. Cf. Rothschild Connected Devices Innovations, LLC v. Guardian Prot. Servs., Inc., 858 F.3d 1383, 1389 (Fed. Cir. 2017) (stating, in the context of finding that a district court abused its discretion in not finding a patent case exceptional, "[t]he conclusory and unsupported statements from Rothschild's counsel and founder that claim 1 of the '090 patent is valid have no evidentiary value").

[30] In the context of determining whether a petitioner was entitled to compensation, a special master evaluated the articles on which Ms. Cottingham is relying and found a lack of persuasive evidence "establishing 'HPV syndrome' as a cognizable injury." Balasco v. Sec'y of Health & Human Servs., No. 17-215V, 2020 WL 1240917, at *30 (Fed. Cl. Spec. Mstr. Feb. 14, 2020). Balasco does not control the outcome of Ms. Cottingham's case because it was a decision about entitlement, not reasonable basis and because Ms. Cottingham's petition does not set forth the claim that she suffered from "HPV syndrome."

The critical factor is that a person with a medical degree, who has the training and experience to diagnose medical problems, did not diagnose Ms. Cottingham with autonomic dysfunction. Ms. Cottingham has not cited, and independent research has not located, any Vaccine Program case in which a non-medically trained petitioner's opinion regarding diagnosis has been credited. This conclusion is consistent with the Federal Circuit's opinion in James-Cornelius. There, although the Court of Appeals recognized that lay people are competent to state when they experienced symptoms, the Federal Circuit did not extend this competency to more complicated medical questions such as diagnosis and causation. James-Cornelius, 984 F.3d at 1380. Without any evidence from a person qualified to diagnose diseases, Ms. Cottingham's assertion that she suffered autonomic dysfunction amounts to "unsupported speculation." See Perreria, 33 F.3d at 1377; see also Sedar, 988 F.3d at 765 (finding an expert's report that a structural defect caused the plaintiff to trip and to fall was more than a scintilla of evidence such that granting a motion for summary judgment was erroneous).

B. **Headaches**

The petition alleges that the HPV vaccine caused Ms. Cottingham to experience headaches. Pet. ¶ 4. According to the petition, on November 1, 2012, Ms. Cottingham "began to have headaches unlike anything she experienced before." Id. November 1, 2012 is approximately four months after Ms. Cottingham received the HPV vaccination on July 5, 2012. Exhibit 3 at 99-100 (vaccination record).

The petition's assertion that Ms. Cottingham's problems began on November 1, 2012, is supported by her affidavit. Exhibit 1. However, the first medical records created after the vaccination indicate that Ms. Cottingham's pediatrician was informed, on November 30, 2012, that Ms. Cottingham had headaches "off and [on] all week." Exhibit 3 at 87. Whether Ms. Cottingham's headaches began around November 23, 2012, as suggested in the pediatrician's November 30, 2012 medical record or Ms. Cottingham's headaches began about three weeks earlier as suggested in her affidavit does not affect the outcome. Even under Ms. Cottingham's version of events, her headaches began approximately four months after the vaccination.

The latency between the vaccination and the onset of headaches influences the outcome to a great degree. Through the package insert, Ms. Cottingham has presented some evidence that the HPV vaccination can cause headaches. But, as the Secretary argues, see Resp't's Br., filed Nov. 19, 2020, at 10, the package insert indicates that the clinical trials link the vaccination to headaches that occur

within 15 days of the vaccination. Specifically, the manufacturer reported that among a population of approximately 7,000 women aged 16-26 years old who received the Gardasil vaccine, 13.7 percent reported headaches within 1 to 15 days. Exhibit A at 6 (table 2).[31] Thus, within the "adverse reports" section, the manufacturer included, among other problems, "headaches." Id. at 1.[32] Thus, the evidence supports a finding at the lower-than-preponderance standard, that Ms. Cottingham possessed a reasonable basis for alleging that the HPV vaccine can cause headaches.

After a petitioner demonstrates that some evidence supports a finding that there is a reasonable basis for alleging that the vaccine can cause an injury, the next step is to consider whether the injury arose in an "appropriate" time. The package insert indicates 1 to 15 days is an appropriate time. Exhibit A at 6 (table 2).

While Ms. Cottingham, as discussed above, argues that an evaluation of the timing is not appropriate in the context of determining whether reasonable basis supports the claims set forth in the petition, see Pet'r's Br., filed Nov. 19, 2020, at 10, Ms. Cottingham also argues that the appropriate onset extends to 5.47 months. Id. at 12 n.1 (citing exhibit 13 (Kinoshita) at 2); see also Tr. 84-85.

Ms. Cottingham's reliance on the Kinoshita article seems unclear. At one point, Ms. Cottingham maintained that the set of medical articles were being offered for the limited purpose of showing that other people have reported experiencing symptoms similar to the symptoms that Ms. Cottingham experienced after the HPV vaccine. Tr. 48. Yet, Ms. Cottingham also offered the Kinoshita article to serve as a reliable indicator for the appropriate interval between vaccination and onset. Tr. 52.

Ms. Cottingham, as the proponent of the evidence and as the party with the burden of proof regarding reasonable basis, McKellar v. Sec'y of Health & Human Servs., 101 Fed. Cl. 297, 305 (2011), has not established that the Kinoshita article is a reliable source of information for the appropriate interval between vaccination

[31] The clinical trial appears not to have considered the number of women who did not receive a vaccination and had a headache.

[32] The manufacturer also reported "headaches" as an "adverse experience" "spontaneously reported during post-approval use of GARDASIL." Exhibit A at 9 (section 6.2). But, for the reasons discussed above, statements in the post-marketing section carry much less, if any, weight regarding causation.

and onset. Ms. Cottingham may legitimately point to publication in a journal that subjects manuscripts to peer review before publication.[33] However, peer review is not dispositive about reliability. Daubert v. United States, 509 U.S. 579, 593-94 (1993) ("The fact of publication (or lack thereof) in a peer reviewed journal thus will be relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised."); see also Terran v. Sec'y of Health & Human Servs., 41 Fed. Cl. 330, 336 (1998) (highlighting the usefulness of the Daubert standards in evaluating reliability of scientific evidence in Vaccine Program cases), aff'd, 195 F.3d 1302, 1316 (Fed. Cir. 1999).

A problem with assigning the Kinoshita article more than a scintilla of weight as to the appropriate temporal interval is the methodology of the Kinoshita researchers. In essence, the Kinoshita article is a series of (forty) case reports. Isolated case reports are the weakest type of evidence regarding causation, meriting little, if any, weight. See Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1254 (Fed. Cir. 2011) (stating the "special master's decision reveals a thorough and careful evaluation of all of the evidence, including . . . reports and medical literature").

Kinoshita's suggestion that the HPV vaccine might cause symptoms that first appear, on average, approximately five months after vaccination is also not consistent with the undersigned's experience as a special master. Setting aside cases in which petitioners appear pro se, petitioners do not typically file petitions in which the latency between vaccination and onset of symptoms is as long as the interval asserted here. When asked during oral argument whether any cases supported an interval of more than four months, Ms. Cottingham's attorney stated that he did not perform that research. Tr. 93. Thus, Ms. Cottingham has not cited any analogous cases.

In the context of determining entitlement, special masters have rejected the time Ms. Cottingham proposes. See, e.g., Phillips v. Sec'y of Health & Human Servs., No. 16-906V, 2020 WL 7767511, at *30 (Fed. Cl. Spec. Mstr. Nov. 23, 2020) (finding a sixteen-week onset in an HPV-ITP case medically not appropriate); Caron v. Sec'y of Health & Human Servs., No. 15-777V, 2017 WL 4349189, at *10 (Fed. Cl. Spec. Mstr. Sep. 7, 2017) (rejecting five-month interval in context of multiple vaccines and the onset of a form of osteomyelits), mot. for

[33] The publisher's website describes the Journal of Internal Medicine as peer-reviewed. https://onlinelibrary.wiley.com/journal/13652796?tabActivePane=

rev. denied, 136 Fed. Cl. 360, 389-90 (2018). In fact, special masters tend to draw a line at a two-month onset. See Conte v. Sec'y of Health & Human Servs., No. 17-403V, 2020 WL 5743696, at *26 (Fed. Cl. Spec. Mstr. July 27, 2020) (rejecting a twelve-week onset in a flu-CIDP case and remarking that eight weeks appears to be the maximum onset time frame deemed reasonable in the Vaccine Program); Pearson v. Sec'y of Health & Human Servs., No. 16-9V, 2019 WL 3852633, at *16 (Fed. Cl. Spec. Mstr. July 31, 2019) (finding, in a flu-TM case, that a "74-day onset period is medically and scientifically unacceptable") (citing cases); Kamppi v. Sec'y of Health & Human Servs., No. 15-1013V, 2019 WL 5483161, at *11 (Fed. Cl. Spec. Mstr. July 24, 2019) (stating that "[s]pecial masters in the Program have not awarded compensation when onset occurs more than two months after vaccination" in flu-GBS cases) (citing cases); Harrington v. Sec'y of Health & Human Servs., No. 14-43V, 2018 WL 4401976, at *35 (Fed. Cl. Spec. Mstr. Aug. 14, 2018) (rejecting, in the alternative, a two-month onset in a claim involving the HPV vaccine); Koehn v. Sec'y of Health & Human Servs., No. 11-355V, 2013 WL 3214877, at *28 (Fed. Cl. Spec. Mstr. May 30, 2013) (rejecting two-month onset in claim involving HPV vaccine), mot. for rev. denied sub. nom., C.K. v. Sec'y of Health & Human Servs., 113 Fed. Cl. 757 (2013), aff'd, 773 F.3d 1239 (Fed. Cir. 2014). Onset of neurologic conditions more than roughly two months after a swine flu vaccination also contributed to rejection of claims in the swine flu compensation program. See, e.g., Kenneda v. United States, 815 F. Supp. 926, 932 (S.D.W. Va. 1993) (rejecting an onset time frame between 2-3 months in a case involving the swine flu vaccination); Benedict v. United States, 785 F. Supp 97, 99 (N.D. Ohio 1991) (same). In some instances, special masters have also rejected time frames shorter than two months. See, e.g., Greene v. Sec'y of Health & Human Servs., 146 Fed. Cl. 655, 667-68 (2020) (affirming the special master's finding that a 41-day onset was "medically unreasonable" in a tetanus-diphtheria vaccine-brachial neuritis case), aff'd, 841 Fed. App'x 195 (Fed. Cir. 2020).

Although those cases addressed timing in the context of determining entitlement, special masters have considered the latency between the vaccination and the onset of symptoms in determining whether reasonable basis supports the claims set forth in the petition. See Kamppi v. Sec'y of Health & Human Servs., No. 15-1013V, 2020 WL 7767513, at *11-12 (Fed. Cl. Spec. Mstr. Nov. 6, 2020) (finding no reasonable basis); Harding v. Sec'y of Health & Human Servs., No. 17-1580V, 2019 WL 3215974, at *7 (Fed. Cl. Spec. Mstr. June 18, 2019) (finding reasonable basis because the petitioner's autoimmune disease worsened within 30 days of receiving a vaccine), mot. for rev. denied, 146 Fed. Cl. 381 (2019); Carter v. Sec'y of Health & Human Servs., No. 16-852V, 2018 WL 6322447, at *9 (Fed. Cl. Spec. Mstr. Oct. 16, 2018) (finding no reasonable basis because, in part, of the

10-month delay between childhood vaccinations and the onset of developmental delay).

Ms. Cottingham contends other cases do not inform whether there was a reasonable basis for her (implicit) claim that a medically appropriate interval between an HPV vaccination and the onset of headaches extends to four months. See Pet'r's Br., filed Nov. 19, 2020, at 10-12; Tr. 93. Those other cases are distinguishable because they involve different vaccines allegedly causing different illnesses.

Ms. Cottingham's distinction is a fair point. However, Ms. Cottingham has not identified any case involving any vaccine-injury combination remotely resembling her claim that a latency of approximately four months is appropriate. Indeed, at some point, the period between a vaccination and an injury can become inherently unreasonable given the basic scientific understanding of how vaccines trigger the immune system. For example, in the December 11, 2020 oral argument, Mr. Downing explicitly disclaimed any reliance in this case on Ozawa's report of temporality, which extended from 1 day to 1532 days, an unreasonably long period of latency between vaccination and injury. Tr. 62. The deviation from the norm present in Ms. Cottingham's case, combined with the relatively commonplace nature of headaches (for example, Ms. Cottingham experienced headaches before she received the HPV vaccination, see exhibit 3 at 55-56 (Mar. 6, 2012)), would seem to heighten the need for some reliable evidence to explain why an approximately four-month latency is reasonable.

Finally, if Ms. Cottingham had presented some reliable evidence that four months is a reasonable latency, Ms. Cottingham's next step as part of a showing of causation in the entitlement phase would be to show "a logical sequence of cause and effect" (Althen prong 2). For prong two, probative evidence can come from treating doctors. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). The two doctors who treated Ms. Cottingham when she complained about headaches attributed the headaches to infections. Exhibit 3 at 87-88 (Nov. 30, 2012), 78 (Jan. 31, 2013). Thus, for Ms. Cottingham's claim that the HPV vaccination caused her headache, the evaluations from the treating doctors cut against a finding of reasonable basis.[34]

[34] The undersigned is aware that James-Cornelius ruled that: "[A]bsence of an express medical opinion on causation is not necessarily dispositive of whether a claim has a reasonable basis[.]" James-Cornelius, 984 F.3d at 1379. Consistent with this statement, the undersigned is not requiring Ms. Cottingham to point to affirmative evidence from a medical professional who

Thus, in short, the package insert, which shows some people developed headaches within approximately *two weeks* of an HPV vaccination, and the medical records and affidavit, which show Ms. Cottingham developed headaches approximately *four months* after vaccination, constitute more than a scintilla of evidence on the proposition that the vaccination caused Ms. Cottingham's headaches. Cottingham, 971 F.3d at 1346 (the "medical records paired with the Gardasil package insert constitutes objective evidence supporting causation"); see also Fourth Opinion, 2021 WL 3085502, at *4 (defining scintilla). But, even at a standard in which petitioners do not have to establish their claims by a preponderance of the evidence, the evidence does not support a finding that Ms. Cottingham carried her burden to present a reasonable basis for the claim that the vaccination caused her headaches.

C. **Fainting**

Ms. Cottingham next alleges that the July 5, 2012 HPV vaccination caused her to suffer fainting episodes on March 29, 2013 and May 23, 2013. Pet. ¶¶ 6-7. Ms. Cottingham's petition seems to link these two fainting episodes to a series of near black outs that began in November 2012. Pet. ¶ 5.

In the context of discussing the affidavit (section V.B above), the undersigned explained why the affidavit's assertion regarding a series of near black outs continuing for months without report in medical records created contemporaneously is unlikely to be credible. Nevertheless, for purposes of examining the reasonable basis for a claim that the July 5, 2012 vaccination caused Ms. Cottingham to suffer fainting, the undersigned will assume the accuracy of the statement that Ms. Cottingham experienced black outs beginning in November 2012.

Even crediting Ms. Cottingham's assertion, the objective support for this claim remains insufficient to find reasonable basis. Like the claim for headaches, the shortest latency for "near black outs" is approximately four months. As explained in the previous section, Ms. Cottingham has not identified any case in which special masters have found, in the entitlement stage, any vaccine can cause

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stated that the vaccination caused her headache. For Ms. Cottingham, the treating doctors identified a cause for her headaches, other than the vaccination. James-Cornelius does not prevent special masters from considering the value of statements from treating doctors that tend to exculpate the vaccine as a cause for a particular condition. See 42 U.S.C. § 300aa–13(a)(requiring special masters to decide issues based on the record as a whole).

black outs starting approximately four months after the vaccination. Thus, Ms. Cottingham's claim remains an outlier.

If the two reported incidents of fainting were considered independent of Ms. Cottingham's assertions of near black outs, the claim that the HPV vaccination caused those fainting episodes becomes even more far-fetched. The two reported incidents of fainting occurred approximately eight months and approximately ten months after the vaccination. Eight and ten months is much longer than the time listed on the product insert. The HPV vaccine's manufacturer warned that vaccine-recipients should be observed for "15 minutes" because syncope might develop. Exhibit A at 3 (section 5.1). The manufacturer did not report syncope in association with the results of clinical trials. Id. at 4-9 (section 6.1).[35]

In oral argument, Ms. Cottingham attempted to distinguish what the manufacturer reported on the product insert from what she experienced. This attempt was largely unsuccessful. Ms. Cottingham stated that the manufacturer was reporting a type of syncope known as "vasovagal syncope." Tr. 19. The evidentiary basis for this assertion is not readily apparent as the product insert uses neither "vaso" nor "vagal." See exhibit A.

Ms. Cottingham's attempted distinction asserts that the syncope she experienced approximately eight and approximately ten months later was a type of syncope known as "postural" syncope. Tr. 19. The "postural" nature of Ms. Cottingham derives, in her view, from the reports in medical records that the syncope is associated with standing and alleviated on sitting. Id.; see also exhibit 3 at 70-71, 80-81, 111. However, Ms. Cottingham informed the cardiologist who treated her about the context in which syncope and near-syncopal episodes occurred. Even with this information, the cardiologist diagnosed her as suffering from vasovagal syncope. Exhibit 3 at 112. While during oral argument Ms. Cottingham dismissed this diagnosis as not supported, Tr. 79-80, Ms. Cottingham has not cited any evidence from a medical professional (as opposed to her attorney's argument) that the syncope she suffered approximately eight and approximately ten months after vaccination was postural.

Even if a medical professional had classified Ms. Cottingham's fainting episodes as "postural," the latency between the HPV vaccination and the earliest fainting episode is long. In Brinth, the "mean delay between vaccination and onset

[35] Syncope is included as part of the post-marketing experience. Id. at 9 (section 6.2). However, no time frame is listed.

of symptoms was 9.3 days (range: 0-30)." Exhibit 12 at 2603. In Blitshteyn, the longest onset between vaccination and the onset of symptoms was two months. Exhibit 14 at 136 (table 1: patient 2). Two months is approximately six months faster than the onset of Ms. Cottingham's first fainting episode. Even two months is a long latency between vaccination and syncope. When the onset of a seizure was eight weeks after vaccination, Dr. Blitshteyn declined to provide an opinion in support of causation. Leonard v. Sec'y of Health & Human Servs., No. 13-668V, 2014 WL 1324596 (Fed. Cl. Spec. Mstr. March 13, 2014). Similarly, a special master was not arbitrary in crediting the opinion of a cardiologist the Secretary had retained who opined that "'10 to 12 hours between vaccination and syncope is too long for there to be a causative relationship.'" Hopkins v. Sec'y of Health & Human Servs., 62 Fed. Cl. 333, 335 (2004) (denying motion for review).

Delays of approximately eight and approximately ten months are well outside patterns commonly presented in Vaccine Program petitions. This latency is a primary reason for finding that Ms. Cottingham's claim that the HPV vaccination caused her fainting episodes lacks reasonable basis.

The other reason for finding that Ms. Cottingham's claim that the HPV vaccine caused her to suffer syncopal episodes is that on both occasions the doctor who treated Ms. Cottingham proposed causes other than the HPV vaccine. Specifically, on March 29, 2013, the doctor assessed Ms. Cottingham as suffering from "gastroenteritis" and "dehydration." Exhibit 3 at 81. Similarly, on May 23, 2013, the doctor stated that Ms. Cottingham suffered from dehydration and noted that she did not eat or drink that morning. Id. at 70. These statements from treating doctors constitute "objective evidence," weighing against a finding that Ms. Cottingham possessed a reasonable basis to assert that the HPV vaccine caused her syncopal episodes.

To be sure, a treating doctor's assessment is just one factor and special masters must consider the record as a whole as well as the totality of circumstances in determining whether objective evidence supports finding a reasonable basis for claims set forth in a petition. Thus, a treating doctor's indication that something other than the vaccine caused an injury merits some consideration. Likewise, a treating doctor's statement that a vaccine caused some injury also carries value. But, neither negative nor affirmative statements resolve the issue by themselves.

Here, Ms. Cottingham has not identified any objective evidence suggesting that the diagnostic conclusions Ms. Cottingham's doctors reached on March 29, 2013, and May 23, 2013, were erroneous. Indeed, when Ms. Cottingham saw a cardiologist for the purpose of exploring the reasons for her syncope, the

cardiologist seemed to endorse the previous diagnoses as the cardiologist also "emphasized aggressive fluid hydration." Exhibit 3 at 112.

To summarize, the package insert, which shows some people developed syncope within approximately *15 minutes* of an HPV vaccination, and the medical records and affidavit, which show Ms. Cottingham developed near black outs approximately *four months* after vaccination (at best), constitute more than a scintilla of evidence on the proposition that the vaccination caused Ms. Cottingham's headaches. Cottingham, 971 F.3d at 1346 (the "medical records paired with the Gardasil package insert constitutes objective evidence supporting causation"); see also Fourth Opinion, 2021 WL 3085502, at *4 (defining scintilla). But, even at a standard in which petitioners do not have to establish their claims by a preponderance of the evidence, the evidence does not support a finding that Ms. Cottingham carried her burden to present a reasonable basis for the claim that the vaccination caused her fainting.

D. **Menstrual Difficulties**

From the group of conditions for which Ms. Cottingham has a diagnosis from a treating doctor, the remaining problem is menstrual difficulties. Ms. Cottingham's petition alleges that the HPV vaccine caused her to suffer menstrual problems in the "latter part of 2013." Pet. ¶ 9. For this assertion, the petition cites Ms. Cottingham's affidavit, exhibit 1.

The medical records are not consistent with the affidavit's assertion as to when Ms. Cottingham experienced menstrual difficulties. Ms. Cottingham has not identified any medical records showing menstrual difficulties in the latter part of 2013.[36] On August 18, 2014, Ms. Cottingham's pediatrician noted that she had her last menstruation on July 25, 2014. Exhibit 3 at 109. This record does not suggest that Ms. Cottingham experienced any menstruation problems close in time to that appointment.

Instead, Ms. Cottingham's medical records indicate that she had a menstrual period in December 2014, but did not have one in January 2015. Exhibit 7 at 7.

[36] The discrepancy between the affidavit and the medical records might be explained by the chronology of when Mr. Downing received medical records. Mr. Downing's timesheets show that a paralegal (RWC) received some records from the University of Alabama-Birmingham Department of Obstetrics and Gynecology on August 4, 2015. After additional inquiries, this same paralegal received additional records on December 15, 2015. Ms. Cottingham signed her affidavit on October 28, 2015. Exhibit 1.

After a doctor prescribed oral contraceptives on April 28, 2015, id. at 9, Ms. Cottingham seemed to return to a "regular" menstrual cycle with the help of oral contraceptives by July 8, 2015. Id. at 11-13 (stating that Ms. Cottingham was "currently using [a contraceptive] for cycle control . . . and is cycling regularly").

The support for the proposition that the HPV vaccination can cause menstrual difficulties rests on potentially unreliable evidence. The manufacturer's product insert does not list any problems with menstrual difficulties either following clinical trials or in the post-marketing experience. See exhibit A. Similarly, the articles from the United States and Denmark do not report recipients of the HPV vaccine began to experience menstrual problems after the vaccination. See exhibit 14 (Blitshteyn), exhibit 12 (Brinth).[37]

On the other hand, the two sequential reports from Japan do report menstrual problems after the HPV vaccination. In the earlier study, Kinoshita and colleagues stated that 35 percent (14 out of 44 women) had "disturbed menstruation." Exhibit 13 at 2. In the follow-up study, Ozawa and colleagues found that nearly 50 percent of the 72 participants suffered menstrual abnormalities. Exhibit 15 at 5 (table 2). Ozawa and colleagues listed menstrual abnormalities among their unverified diagnostic criteria. Id. at 4 (table 1). Neither Kinoshita nor Ozawa report any information about the latency between the HPV vaccination and the beginning of menstrual problems specifically.

In Ms. Cottingham's case, the amount of time between her July 5, 2012 HPV vaccination and the onset of menstrual difficulties around January 2015 is approximately two and a half *years*. It is difficult to fathom how the July 5, 2012 HPV vaccine can cause a problem that started more than two years later. This temporal relationship is quite possibly the longest temporal interval proposed in any case in which an attorney represented a petitioner in the undersigned's tenure. The undersigned is not aware of any credible medical theory, offered in any circumstance, that might come close to explaining how the latency could extend to 30 months.

To be fair, the October 30, 2015 petition does not allege that the July 5, 2012 HPV vaccination caused menstrual difficulties beginning in January 2015. The petition actually alleges that the menstrual difficulties began near the end of 2013.

[37] Based upon the questionnaires the participants answered, the Brinth researchers reported that before the vaccination, all participants either used oral contraceptives or had irregular periods. Exhibit 12 at 2604. The Brinth group did not report any aggravation of menstrual problems.

Pet. ¶ 9. If this assertion were accurate, then the latency between the July 5, 2012 HPV vaccination and the onset of menstrual difficulties (assumed to be November 15, 2013) would be still be approximately 16 months. While 16 months is obviously shorter than 30 months, 16 months remains far beyond the temporal interval any special master has recognized.

Finally, to extend an extra benefit to Ms. Cottingham, it might be assumed that after Ms. Cottingham's attorney obtained additional records from the gynecologist around December 15, 2015, Ms. Cottingham might have amended her petition to allege that the second (not first) dose of the HPV vaccine caused her menstrual difficulties.[38] The second dose of the HPV vaccine was administered to Ms. Cottingham on August 18, 2014. Exhibit 3 at 109-10. If it is assumed that Ms. Cottingham's menstrual difficulties began on January 1, 2015, then the latency is approximately 4.5 months.

An interval of approximately 4.5 months is outside the scope of intervals that special masters have credited for reasons explained above in the context of Ms. Cottingham's claim that the first dose of the HPV vaccine caused her headaches. While a latency of 4.5 months falls within the range Kinoshita reported, the Kinoshita methodology is suspect and has not been defended by any witness in this case. Consequently, for an array of different intervals, Ms. Cottingham has not met her burden of establishing the reasonable basis for alleging her menstrual difficulties arose in a time for which an inference of causation is appropriate.

VII. Additional Remarks, including Comments on Denying Fees despite a Finding of Reasonable Basis as a Matter of Discretion

For the reasons explained above, Ms. Cottingham has not met her burden of establishing a reasonable basis for the claims set forth in her petition. In reaching this conclusion, the undersigned has attempted to comply with instructions from appellate authorities at the Federal Circuit and the Court of Federal Claims. In this respect, the undersigned has attempted to consider everything that a special master is supposed to consider in evaluating whether a reasonable basis supports the claims set forth in Ms. Cottingham's petition. The list of considered topics includes, but is not necessarily limited to, the petition, Ms. Cottingham's affidavits, the medical records, the Secretary's report, the package insert, the medical articles

[38] Ms. Cottingham did not amend her petition before filing a motion to dismiss on October 6, 2016.

filed after the Federal Circuit's remand, the opinions of the Federal Circuit and the Court of Federal Claims in this case, all the parties' briefs, the opinion of the Federal Circuit in James-Cornelius, the policies underlying the Vaccine Act, the novelty of the HPV vaccine, and the Althen factors for structure. Yet, at the same time, the undersigned has attempted to refrain from considering factors that appellate authorities have said special masters should not consider when evaluating reasonable basis, such as the pendency of the statute of limitations, the lack of a statement from a treating doctor who linked the vaccination to any health problem, and the lack of an opinion from a doctor retained in this litigation supporting causation.

In this regard, the undersigned acknowledges that the January 7, 2021 decision pointed to the lack of a report from a treating doctor or retained expert as one reason for finding that Ms. Cottingham's case lacked a reasonable basis. Fourth Fees Decision, 2021 WL 347020, at *18. While the Federal Circuit's use of the term "necessarily" in the phrase "absence of an express medical opinion on causation is not necessarily dispositive of whether a claim has a reasonable basis," James-Cornelius, 984 F.3d at 1379, raises questions about whether there are any circumstances in which a special master may consider the lack of an explicit statement from a treating doctor or retained expert saying a vaccine caused an injury, the present decision does not rest in any respect on the lack of a statement from a treating doctor or retained expert suggesting the vaccine caused any injury.

The main reason Ms. Cottingham's case lacks a reasonable basis is that the latency between the vaccination and the onset of any health conditions was approximately four months at the shortest. The January 7, 2021 decision emphasized: "The long latency weighs heavily." Fourth Fees Decision, 2021 WL 347020, at *39. Neither the Federal Circuit's opinion nor any of the remands from the Court of Federal Claims bar the undersigned from evaluating the time between the vaccination and the start of health problems.

In looking to the latency between the vaccination and the onset of the various symptoms, the undersigned is following, in some respects, the path laid out in Perreira. There, as noted above, the special master denied entitlement because there was no support for their expert's opinion that DPT causes harm that would first appear two weeks later. Perreira, 1991 WL 117740, at *1, 1 n.2. Then, in looking at whether there was a reasonable basis for the claim, the special master found that the expert's opinion was "unsupported speculation" and found no reasonable basis. Perreira, 1992 WL 164436, at *2. On appeal, the Federal Circuit

determined that the special master was not arbitrary in finding that reasonable basis was not established. Perreira, 33 F.3d at 1377.[39]

In somewhat similar fashion, the undersigned is also relying upon the latency between the vaccination and the onset of various problems in Ms. Cottingham's case and finding that the proposed latency is far beyond the norm. The undersigned's view of what is typically proposed as an appropriate temporal relationship derives from the experience in adjudicating cases. The January 7, 2021 decision also indicated that special masters should be allowed to rely upon their experience in evaluating reasonable basis. Specifically, that decision stated:

> The experience of the presiding judicial officer seems to be a factor useful in evaluating whether the claims in a petition were supported by reasonable basis. See Highmark Inc. v. Allcare Health Mgmt. Sys., Inc., 572 U.S. 559, 564 (2014) (interpreting a provision of the Patent Act, 35 U.S.C. § 285, authorizing attorneys' fees in "exceptional cases" and stating that district courts are "better positioned to determine whether a case is exceptional because it lives with the case over a prolonged period of time"); Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1104 (Fed. Cir. 1996) (allowing special masters to use their "accumulated expertise" in determining whether to find entitlement to compensation); Saxton v. Sec'y of Health & Human Servs., 3 F.3d 1517, 1521 (Fed. Cir. 1993) (allowing special masters to use their experience in determining the reasonableness of the amount of attorneys' fees and costs); cf. Silva v. Sec'y of Health & Human Servs., 108 Fed. Cl. 401 (2012) (reviewing a finding of no reasonable basis under the broad abuse of discretion standard). Based upon this experience, Ms. Cottingham's claim that the HPV vaccine caused an injury that first appeared approximately four months after the vaccination is an outlier.

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[39] As a precedential opinion from the Federal Circuit, Perreira remains binding. However, it is not so easy to reconcile the outcome in Perreira, which determined that the special master could find no reasonable basis despite the presence of an expert's report with the suggestion in James-Cornelius that a special master should not consider whether a petitioner even has an expert report. See Strickland v. United States, 423 F.3d 1335, 1338 & n.3 (Fed. Cir. 2005) (discussing adherence to the reviewing court's precedent).

Fourth Fees Decision, 2021 WL 347020, at *40. In Ms. Cottingham's briefs regarding the motion for review, Ms. Cottingham did not contest the proposition that special masters may rely upon their experience. See Pet'r's Br., filed Feb. 5, 2021; Pet'r's Reply, filed Mar. 15, 2021. The Court's Fourth Opinion also did not bar the undersigned from relying upon experience in evaluating claims of reasonable basis.

Other factors that contribute to the finding that Ms. Cottingham's case lacked a reasonable basis include the lack of diagnosis to support the assertion of dysautonomia (meaning no unifying syndrome) and the presence of alternative causes in the medical records (viral infections for the headaches and dehydration for the fainting). These deficiencies are not cured by the subjective belief of Ms. Cottingham or her attorney. As the Federal Circuit has stated, "the extent of a party's pre-suit investigation or how fervently it believed in its allegations does not affect the objective strength of that party's litigating position." Nova Chems. Corp. v. Dow Chem. Co., 856 F.3d 1012, 1018 (Fed. Cir. 2017) (affirming award of attorneys' fees), cert. denied, 138 S. Ct. 485 (2017).

Eliminating the lack of an explicit statement from a treating doctor or a retained expert does not affect the other problems weighing against a finding of reasonable basis. Thus, simply disregarding the omission of a direct statement from a medical professional does not mandate a switch in outcome. See Carter v. Sec'y of Health & Human Servs., 132 Fed. Cl. 372, 382 (2017) (denying motion for review and indicating that special master's consideration of lack of support from doctors was harmless error because the evidence did not support a finding of reasonable basis).

Nevertheless, the undersigned recognizes that appellate authorities might reach different results on the evidentiary issue and conclude that the finding of no reasonable basis here constituted an abuse of discretion. See, e.g., Adjustacam, LLC v. Newegg, Inc., 861 F.3d 1353 (Fed. Cir. 2017) (ruling that district court abused its discretion in finding a patent case not exceptional). A finding that reasonable basis supports the claims set forth in Ms. Cottingham's would make her eligible for an award of attorneys' fees and costs.

A petitioner's eligibility for an award of attorneys' fees and costs, however, does not absolutely guarantee an award. The Vaccine Act states that upon a finding of good faith and reasonable basis, a special master "may award" reasonable attorneys' fees and costs. 42 U.S.C. § 300aa–15(e)(1). The word "may" differs from the word "shall," which the Vaccine Act uses in the context of directing special masters to award reasonable attorneys' fees and costs to

petitioners who receive compensation. See Hellenbrand v. Sec'y of Health & Human Servs., 999 F.2d 1565, 1570 (Fed. Cir. 1993) (distinguishing "shall" from "may"). Thus, the Federal Circuit recognized that "even when these two requirements [good faith and reasonable basis] are satisfied, a special master retains discretion to grant or deny attorneys' fees." James-Cornelius, 984 F.3d at 1379. Citing this portion of James-Cornelius, the Secretary's response to the most recent motion for review argued that any error in the undersigned's evaluation of reasonable basis was harmless because the undersigned could have denied attorneys' fees and costs as a matter of discretion anyway. Resp't's Resp., filed Mar. 8, 2021.

However, the undersigned is not aware of any case in which a special master (a) found good faith and a reasonable basis for the claims set forth in the petition and (b) denied attorneys' fees. Thus, while it may be correct to say that a finding of good faith and reasonable basis makes a petitioner "eligible" for an award of reasonable attorneys' fees and costs, in practice these twin findings have led to an award of attorneys' fees and costs. If there is an exception to this apparently universal practice, the Secretary did not cite the case(s). In the circumstances of Ms. Cottingham's case, if the undersigned found that Ms. Cottingham had met her burden of establishing a reasonable basis for the claims set forth in her petition---a burden that is markedly less than the preponderance of the evidence standard---then the undersigned would have awarded her reasonable attorneys' fees and costs.

Accordingly, in recognition of the possibility that an appellate authority might determine that Ms. Cottingham has satisfied the reasonable basis standard and to promote judicial efficiency in any appellate process, the undersigned next determines a reasonable amount of attorneys' fees and costs to which Ms. Cottingham would be entitled.

VIII. Reasonable Amount

As Ms. Cottingham has litigated her eligibility for an award of attorneys' fees and costs, the amount that Ms. Cottingham has requested has, naturally, increased. On this remand, she submitted an additional supplemental motion for attorneys' fees and costs on August 9, 2021.

In the decision issued on January 7, 2021, the undersigned determined a reasonable amount of attorneys' fees and costs for work performed prior to October 12, 2020, totaled $85,177.62, consisting of $77,072.50 in attorneys' fees and $8,105.12 in attorneys' costs.

Also in the January 7, 2021 decision, the undersigned assessed additional reasonable attorneys' fees and costs at $15,959.00 in attorneys' fees and $1,106.58 in costs, based on the Ms. Cottingham's supplemental motion filed on January 4, 2021. Therefore, the total reasonable attorneys' fees and costs prior to this remand proceeding came to $102,243.20.[40]

August 9, 2021 Motion for Supplemental Fees

Ms. Cottingham filed a supplemental motion for attorneys' fees and costs on August 9, 2021. The Secretary did not respond to this motion. In that motion, she requested an additional $21,772.50 in attorneys' fees and $2,633.61 in costs. The undersigned finds both amounts reasonable. Therefore, when added to the previously considered amounts, the total of attorneys' fees and costs comes to $126,649.11, representing $114,804.00 in fees and $11,845.31 in costs.

IX. Conclusion

For the reasons explained above, Ms. Cottingham's petition asserts claims that reasonable basis does not support. Accordingly, her motion for attorneys' fees and costs is DENIED. Pursuant to Vaccine Rule 28.1(a), the Clerk's Office is directed to provide this decision to the assigned judge.

IT IS SO ORDERED.

s/ Christian J. Moran
Christian J. Moran
Special Master

[40] For a more detailed discussion of reasonable attorneys' fees and costs requested prior to this remand, see Fourth Fees Decision, 2021 WL 347020, at *40-42.