

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

CHAD SHELLER, as personal	*	
representative of the Estate of	*	
DANIEL ELIAS SHELLER,	*	
	*	No. 18-696V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	Filed: August 15, 2022
	*	
SECRETARY OF HEALTH	*	Attorneys' fees and costs;
AND HUMAN SERVICES,	*	reasonable basis
	*	
Respondent.	*	

Anne C. Toale, Maglio Christopher & Toale, Sarasota, FL, for petitioner;
Christine M. Becer, United States Dep't of Justice, Washington, DC, for
respondent.

PUBLISHED DECISION DENYING ATTORNEYS' FEES AND COSTS¹

After Mr. Sheller dismissed his case voluntarily, he sought an award of attorneys' fees and costs as the Vaccine Act allows. The Secretary has objected because Mr. Sheller has not established that he is eligible for such an award due to a lack of reasonable basis.

¹ The E-Government Act, 44 § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website (<https://www.uscfc.uscourts.gov/aggregator/sources/7>). Once posted, anyone can access this decision via the internet. 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 be reflected in the document posted on the website.

As explained below, Mr. Sheller has not met the burden of establishing reasonable basis for the claim set forth in the petition. The petition alleged the hepatitis B, diphtheria-tetanus-acellular pertussis (“Dtap”), inactivated polio (“IPV”), and haemophilus influenza type B (“Hib”), and Prevnar 13 vaccines his son, Daniel, received on April 15, 2016, June 14, 2016, and June 21, 2016, caused his son’s death.

However, Mr. Sheller has not submitted a sufficient quantum of probative evidence to show that the general proposition that childhood vaccines can cause an unexpected death is reasonably supported. Moreover, Mr. Sheller did not supply sufficient evidence to support the reasonable basis of the claim the vaccines caused Daniel’s unfortunate death. Accordingly, Mr. Sheller’s motion is DENIED.

I. Background

A. Medical History

Daniel’s life was tragically short. He was born on April 14, 2016, and died on June 23, 2016. Exhibit 2 at 2, 4.

Before Daniel died, his pediatrician evaluated him on April 19, 2016, April 26, 2016, and June 14, 2016. Exhibit 1 at 3-8. The pediatrician did not identify any concerns that were implicated in Daniel’s death.

During the June 14, 2016 well-baby appointment, Daniel received the Pentacel vaccine. Exhibit 1 at 2-4. A week later, Daniel received the Prevnar 13 vaccine. Id. at 2 (June 21, 2016).

On June 23, 2016, Daniel was placed face-up on a couch with a blanket around 11:00 A.M. Exhibit 3 at 3. The caregiver called emergency medical services at 1:43 P.M. and when they arrived Daniel did not have a pulse and was not respiring. Exhibit 2 at 25; exhibit 3 at 8. Daniel was transported to a hospital. There, doctors attempted to revive him but were not successful. Exhibit 2 at 2-4. The initial diagnosis was “[s]udden death uncertain causation.” Id. at 4.

Dr. Montez performed an autopsy on June 29, 2016. Dr. Montez did not determine a cause of death. Exhibit 3 at 12, 16. The brain weight was normal (780 grams). Id. at 19. Daniel’s lungs showed dependent congestion. Id. at 20.

B. Procedural History

1. Merits

Within four days of Daniel's death, Mr. Sheller had retained John Caldwell, an attorney at Maglio, Christopher & Toale, P.C. See exhibit 8 (timesheets).² Among Mr. Caldwell's first tasks was a "Telephone conference with coroner's office re: delay of autopsy pending lab instructions."

Over the next month, Mr. Caldwell continued to correspond with the coroner's office and other labs regarding possible testing. Meanwhile, paralegals collected Daniel's medical records. In November 2016, Mr. Caldwell reviewed the autopsy record.

In December 2016, Mr. Caldwell conferred with an immunologist. He more intensely engaged with an expert in March and April 2017. Time entries from this time mentioned Dr. Akbari.

About one year later, Mr. Caldwell reviewed a preliminary assessment from Dr. Akbari (April 3, 2018). Paralegals also pursued medical records.

Mr. Caldwell drafted a petition, which was filed on May 17, 2018. This date is approximately 23 months after Daniel died. The petition alleged that the Pentacel and Prevnar 13 vaccines caused Daniel's death. Pet. ¶¶ 2, 9.³

Mr. Sheller's motion for fees emphasizes that before Mr. Caldwell filed a petition, a special master had found childhood vaccines caused an infant's death. Boatmon v. Sec'y of Health & Hum. Servs., No. 13-611V, 2017 WL 3432329 (Fed. Cl. Spec. Mstr. July 10, 2017). In doing so, the special master credited an opinion offered by Douglas Miller, a pathologist. To Mr. Sheller, the special master's ruling supports a finding of reasonable basis. Oral Arg. Tr. at 39-40. However, the Secretary maintains Boatmon affects good faith only. Id. at 43.

Less than one week after Mr. Caldwell submitted the petition, Mr. Caldwell filed exhibits 1-6 on behalf of Mr. Sheller. This set of exhibits includes Dr.

² Information about the activities of Mr. Sheller's attorneys can be found in the timesheets, which are not again cited in this Decision.

³ The petition also mentions that Daniel received the hepatitis B vaccine when he was born. However, the arguments regarding the reasonable basis for the claims set forth in the petition do not involve the hepatitis B vaccine given at birth.

Akbari's preliminary assessment, dated April 4, 2018. Dr. Akbari's letter is an important piece of evidence in weighing whether Mr. Sheller has met his burden regarding reasonable basis.

Dr. Akbari stated he had reviewed the medical records and summarized them in one paragraph. Dr. Akbari wrote: "While it is premature to make any conclusions at this stage, I certainly believe it is reasonable to request additional tests on the clinical samples obtained from the patient." Exhibit 5 at 1. Dr. Akbari offered reasons for requesting additional tests. Dr. Akbari repeated his recommendation for additional testing: "While I cannot draw any definitive conclusions at this stage, based on the findings of the autopsy, the absence of any pre-death clinical issues, and my previous research as to potential causes of death following Prevnar 13, I believe it is medically reasonable to request additional tests on the autopsy clinical samples currently in bio-storage." *Id.* at 2. After describing where those additional tests could be conducted, Dr. Akbari closed his letter to Mr. Caldwell by stating: "In summary, I firmly believe at this juncture that, based on the substantial pulmonary edema in this two-month-old with no apparent cause other than the vaccines, it is reasonable to conduct further inquiry including laboratory work I have recommended here and previously." *Id.*

Arguably, the next important event occurred outside of the four corners of the Sheller case. On July 3, 2018, a judge from the Court of Federal Claims granted a motion for review in Boatmon. The judge ruled that the special master improperly applied the standard of proof as required in vaccine cases when he departed from the decisions of other special masters in deciding to credit the theory advanced by Dr. Miller, considering that Dr. Miller's theory had not been accepted by other SIDS experts. Boatmon v. Sec'y of Health & Hum. Servs., 138 Fed. Cl. 566, 571-72 (2018). The Court found issue with the special master's lack of acknowledgement of other vaccine cases reaching opposite conclusions. *Id.* As such, the court held that "the Special Master in this case ha[d] applied a standard so low as to constitute clear error." *Id.* at 572.

The outcome in Boatmon at the Court of Federal Claims did not halt Mr. Sheller's case. The Secretary evaluated the evidence and recommended against compensation. Resp't's Rep., filed Dec. 7, 2018. The Secretary specifically argued that Dr. Akbari's letter did not support causation. *Id.* at 5.

The parties planned to test some of Daniel's tissues. Order, issued Dec. 20, 2018. Mr. Caldwell researched causes of sudden infant death syndrome for more than seven hours. Fee exhibit 8 at 10 (entries for February 2-8, 2019). A paralegal

attempted to get material from the local sheriff's office. Mr. Sheller was granted authority to obtain autopsy slides. Order, issued Mar. 28, 2019.

In May 2009, the managing partner of the law firm reviewed the case. He assigned the case to Anne Toale, who has acted as counsel of record for the remainder of this case. Ms. Toale and staff continued their attempts to get additional material from the autopsy. In the oral argument regarding petitioner's pending motion for attorneys' fees and costs, Ms. Toale maintained that in infant death cases it is "impossible" to obtain autopsy material without a subpoena. Oral Arg. Tr. at 35. She noted that attorneys in such cases often seek to obtain additional cuts of slides to identify additional tissues for experts to examine. *Id.* at 42-43.

Ms. Toale began working with Dr. Miller in July 2019. Dr. Miller anticipated reviewing autopsy slides in August 2019. Pet'r's Status Rep., filed July 26, 2019. In early September, Dr. Miller reviewed autopsy slides for 2.5 hours. Fee exhibit 9 at 40. Dr. Miller communicated with Ms. Toale the next day for 15 minutes and Dr. Miller's email was later filed as exhibit 20.

On November 7, 2019, the Federal Circuit affirmed the judgment in Boatmon. While the Federal Circuit agreed with the outcome (a denial of compensation), the Federal Circuit did not entirely agree with the reasoning of the judge. The Federal Circuit held that the judge was incorrect in requiring that the special master distinguish his ruling from decisions of other special masters. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1358 (Fed. Cir. 2019). Further, the Federal Circuit held that the judge was incorrect in implying that special masters must apply Daubert standards in assessing expert testimony and that all Daubert factors must be satisfied. *Id.* at 1359. On the other hand, the Federal Circuit ruled that the special master "deviated from the correct 'reputable,' 'sound and reliable' standard and articulated a lower 'reasonable' standard." *Id.* at 1359.

In the months after Boatmon was issued, Ms. Toale communicated with Mr. Sheller, Dr. Miller, and toxicology labs multiple times. It appears that these efforts were not fruitful as Mr. Sheller determined he could not establish his case. Pet'r's Mot. to Dismiss, filed Jan. 10, 2020.

Based upon Mr. Sheller's motion, the case was dismissed. Decision, 2020 WL 618547 (Jan. 13, 2020). At the time of the dismissal, the record included seven exhibits.

2. Fees Litigation

Mr. Sheller requested an award of attorney's fees and costs. Pet'r's Mot., filed March 19, 2020. Ms. Toale maintained that Dr. Akbari's letter established reasonable basis. Exhibit 11 ¶ 22. With that motion, Mr. Sheller submitted five affidavits to substantiate the amount requested. Exhibits 8-12.

The Secretary's initial response was his generic response. The Secretary stated he "is satisfied the statutory requirements for an award of attorneys' fees and costs are met." Resp't's Resp., filed Apr. 2, 2020, at 2. The Secretary also did not interpose any specific objections regarding the amount requested.

The undersigned had questions about the positions of both parties. Accordingly, the parties were directed to file additional briefs. Order, issued July 28, 2020.

Mr. Sheller developed his arguments regarding reasonable basis. Pet'r's Supp., filed Aug. 24, 2020. With this submission, Mr. Sheller also submitted six new exhibits, including the package insert for the vaccines Daniel received, Pentacel and Prevnar 13. Mr. Sheller emphasized Dr. Akbari's report. But, Mr. Sheller also explained "Dr. Miller's assessment led to the claim's dismissal." Pet'r's Supp. at 16.

The Secretary addressed Dr. Akbari. He argued: "Dr. Akbari's statement is . . . merely speculation that petitioner may have a claim, and by itself does not establish reasonable basis." Resp't's Resp., filed Sept. 23, 2020, at 3.

A lengthy delay ensued for which the undersigned is responsible and for which the undersigned apologizes. Upon review, the undersigned had additional questions. Order, issued Aug. 23, 2021.

Mr. Sheller again advanced arguments regarding reasonable basis. Pet'r's Memo., filed Nov. 22, 2022. With this submission, Mr. Sheller filed more than 25 additional articles. Exhibits 20-58. Of this group, Mr. Sheller relies most heavily upon a September 9, 2021 email from Dr. Miller to Ms. Toale. Dr. Miller stated he had reviewed the autopsy including the slides. He stated: "this is a classical case of SIDS." Exhibit 20. He also indicated "there are no sections of medulla to prove any structural abnormality, and there are no good sections of each hippocampus to evaluate for dentate gyrus dysplasia. I could write a report based on statistics from Dr. Kinney's work . . . But this gets us no further than Boatmon and we are all waiting [for] the appellate court to issue a decision." Id. He concluded: "Let me know if you want me to do more." Id.

The Secretary responded. Relying upon Goodgame v. Sec’y of Health & Hum. Servs., 157 Fed. Cl. 62 (2021), the Secretary “move[d] to strike medical articles that petitioner filed after the entitlement stage ended.” Resp’t’s Resp, filed Dec. 22, 2021, at 1. The Secretary further argued that “petitioner has failed to present more than a scintilla of evidence in this case to satisfy Althen prong one.” Id. at 5.

Mr. Sheller’s reply primarily maintained that the Secretary’s motion to strike medical articles filed after entitlement should be denied. Pet’r’s Reply, filed Jan. 8, 2022.

An oral argument was held on June 7, 2022. See order, issued Apr. 26, 2022. One day before the oral argument, Mr. Sheller submitted a notice of additional authority identifying cases discussing reasonable basis. With the completion of oral argument, the case is ready for adjudication.

II. Analysis

This case presents challenging questions. The first concerns the Secretary’s motion to strike medical articles filed after the decision denying entitlement was issued. The Secretary’s position is well grounded for most, and possibly all, of exhibits 13-58. The second is whether cases, such as Boatmon, contribute to the reasonable basis analysis. The third and final question is whether the record, as properly defined, supports the claim set forth in Mr. Sheller’s petition. The answer to this final question is no, for the reasons set forth in section C.

A. Motion to Strike

The Federal Circuit has not decided whether during the fee litigation, petitioners may add exhibits that arguably support the claim for which the petition has been filed. Goodgame is the only (non-binding) precedent from the Court of Federal Claims.

In Goodgame, the special master denied petitioner compensation for failure to prove that the effects of the alleged vaccine injury lasted for more than six months as required by the Vaccine Act. Goodgame v. Sec’y of Health & Hum. Servs., 157 Fed. Cl. 62, 66 (2021). Even after filing a petition and an amended petition, the petitioner failed to submit medical evidence that substantiated the claim that the residual effects of the vaccine injury lasted more than six months. Id. at 70.

The petitioner sought attorneys' fees and costs. In support of her motion, the petitioner submitted two medical articles that were not included when entitlement was being considered. *Id.* at 72 (stating "the docket entries in this case show that a full 14 months AFTER the Special Master issued his decision denying compensation, . . . counsel for Petitioner submitted two medical journal articles in the attorneys' fee proceedings in an attempt to bolster his assertion that there was a reasonable basis for Petitioner's claim."). The special master subsequently denied petitioner's motions for attorneys' fees and costs because the evidence in the record did not satisfy the reasonable basis standard. *Id.* at 64.

Petitioner filed a motion for review of the decision not awarding attorneys' fees and costs. *Id.* at 66. The Court rejected the petitioner's attempt to bolster her claim with articles filed after entitlement was resolved: "[t]he Court [was] at a complete loss as to how Petitioner's counsel believe[d] [that evidence] submitted AFTER judgment on the merits was entered could possibly help form a reasonable basis for Petitioner's claim." *Id.* at 73. The Judge emphasized that "the time for introducing these articles was BEFORE the Special Master issued his ruling on the merits, when they could aid his client's attempt to be compensated for her alleged injury, not AFTER his client had lost on the merits and they could only aid his attempt to collect fees." *Id.* Ultimately, the Court affirmed the special master's decision denying attorneys' fees and costs. *Id.* at 74.

Goodgame's emphasis on petitioners' obligation to present evidence supporting the claim for which the petition was filed while entitlement is pending is consistent with the structure of the Vaccine Act. "Congress expected petitioners to file front-loaded petitions with 'supporting documentation, demonstrating' five elements." Carter v. Sec'y of Health & Hum. Servs., No. 15-1030V, 2017 WL 490427, at *3 (Fed. Cl. Spec. Mstr. Jan. 10, 2017) (quoting 42 U.S.C. 11(c)(1)), mot. for rev. denied, 132 Fed. Cl. 372 (2017). In this way, "Special masters consistently make fee determinations on the basis of the extensive documentation required by § 300aa-11(c) and included with the petition." Sebelius v. Cloer, 569 U.S. 369, 381-82 (2013). While petitioners may rely upon materials not filed contemporaneously with the petition, petitioners and their attorneys are taking a "risk of not being compensated for attorneys' fees and costs if they file without the necessary supporting documentation and are later unable to produce such documentation." Everett v. Sec'y of Health & Hum. Servs., No. 91-1115, 1992 WL 35863, at *2 (Cl. Ct. Spec. Mstr. Feb. 7, 1992).

Drawing a line at the point of a decision resolving entitlement seems to be a natural and sensible demarcation. Attorneys representing petitioners should submit any evidence that could help their clients receive compensation when the client's

case remains pending. A purpose of the Vaccine Program is to compensate people injured by vaccines. Bruesewitz v. Wyeth LLC, 562 U.S. 223, 228 (2011). A secondary purpose is “to ensure that vaccine-injured claimants will have readily available a competent bar to prosecute their claims under the Act.” Saunders v. Sec’y of Health & Hum. Servs., 35 F.3d 1031, 1035 (Fed. Cir. 1994). But, the payment of fees is “secondary” to the primary purpose, which is to compensate deserving individuals.

Requiring evidence relevant to the topics set forth in § 11(c)(1) to be filed during the entitlement phase also is in accord with the Supreme Court’s admonition that a request for attorneys’ fees should not result in a second major litigation. Hensley v. Eckerhart, 461 U.S. 424, 437 (1983). Although the Federal Circuit has not yet defined the limits of this constraint in the context of a case from the Vaccine Program, the Federal Circuit has followed this directive in a variety of other circumstances. Therasense, Inc. v. Becton, Dickinson & Co., 745 F.3d 513, 517 (Fed. Cir. 2014) (whether a patentee’s inequitable conduct allowed an award of attorneys’ fees); Bywaters v. United States, 670 F.3d 1221, 1228-32 (Fed. Cir. 2012) (whether the Court of Federal Claims reasonably determined an amount of attorneys’ fees and costs); Patrick v. Shinseki, 668 F.3d 1325, 1329-30 (Fed. Cir. 2011) (whether the position of the United States was substantially justified); Vaughn v. Principi, 336 F.3d 1351, 1354 (Fed. Cir. 2003) (whether a person pursuing veterans’ benefits was a prevailing party under the Equal Access to Justice Act).

Here, Mr. Sheller has attempted to expand the record to substantiate his claim for attorney’s fees and costs. Before the entitlement decision Mr. Sheller had submitted seven exhibits, consisting of five medical records plus Dr. Akbari’s letter and curriculum vitae. As Mr. Sheller acknowledged, he was not prohibited from filing any evidence during the entitlement phase. Oral Arg. Tr. at 18. After the entitlement decision, Mr. Sheller submitted more than 40 additional exhibits. Exhibits 13-58.⁴

If the evidence regarding the reasonable basis for the claims set forth in the petition were limited to the evidence submitted during the entitlement phase, the Secretary’s motion to strike should be granted in its entirety. Such a result would be consistent with Goodgame, and a case decided more recently by a special master, Contreras v. Sec’y of Health & Hum. Servs., No. 19-491V, 2022 WL

⁴ The cited additional exhibits do not include the five exhibits regarding the amount of fees.

2302208, at *9 (Fed. Cl. Spec. Mstr. May 31, 2022). Furthermore, this result would be consistent with Simmons v. Sec’y of Health & Hum. Servs., 875 F.3d 632, 635 (Fed. Cir. 2017), in which the Federal Circuit indicated that special masters should decide questions of reasonable basis based upon objective evidence. However, this result could be perceived as unduly harsh to Ms. Toale, who argues that, because Boatman was on appeal, it was prudent to wait to submit all evidence on reasonable basis and good faith to preserve Vaccine Program resources. Oral Arg. Tr. at 16. Ms. Toale also argued that although she could have filed the additional evidence during the entitlement phase, it would not have made sense because one cannot prevail on entitlement without having an expert examine the medical literature and package inserts. Id. at 18. But see Carter, 2017 WL 490427 at *1 (finding that a petition alleging vaccines caused an infant’s death lacked a reasonable basis). To allow Mr. Sheller and Ms. Toale to present their strongest argument that reasonable basis supported the claim set forth in the petition, the motion to strike will be denied for all exhibits that appear relevant.

A focus on relevance complies with Vaccine Rule 8, which states: “In receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties.” Vaccine Rule 8(b)(1). Although the Vaccine Rules do not define “relevant evidence,” the Federal Rules of Evidence indicate that “relevant evidence” has “any tendency to make a fact more or less probable than it would be without the evidence.” Fed. R. Evid. 401; accord Cox v. Sec’y of Health & Hum. Servs., 30 Fed. Cl. 136, 143 (1993).

Mr. Sheller’s briefs help to show whether an article is relevant. If Mr. Sheller discussed an article in a brief, then the article is relevant and remains in the record. On the other hand, simply dumping dozens of articles into the case file without explaining the article’s significance does not make an article relevant. In other words, for articles that Mr. Sheller’s briefs do not discuss, Mr. Sheller has waived any argument regarding the article’s relevance. See Vaccine Rule 8(f). Because those undiscussed articles have not been shown to be relevant, they are struck from the record after having been reviewed. For a complete list of articles that are struck and a short explanation regarding the lack of relevance, see the appendix. The remaining articles have been considered.

B. Whether Decisions Constitute Evidence Relevant to Determining Whether a Reasonable Basis Supports the Claim Set Forth in the Petition

The Federal Circuit has determined that reasonable basis depends upon objective evidence. Simmons, 875 F.3d at 635. In addition to Daniels's medical records, the letter from Dr. Akbari, the email from Dr. Miller, the package inserts, and various medical articles, Mr. Sheller argues that the special master's decision in Boatmon supports reasonable basis.

However, when asked at oral argument whether a case constitutes evidence relevant to deciding reasonable basis, attorneys for both parties struggled. Oral Arg. Tr. at 39, 44. "Evidence" is defined as "1. Something (including testimony, documents and tangible objects) that tends to prove or disprove the existence of an alleged fact" and as "3. The collective mass of things esp. testimony and exhibits, presented before a tribunal in a given dispute." Black's Law Dictionary (11th ed. 2019).

A ruling finding entitlement or a decision denying entitlement typically analyzes "evidence" in that case. "Evidence" typically includes medical records, testimony, reports from experts and articles published in peer-reviewed journals. Thus, a case, such as Boatmon, can guide parties in future cases to experts and articles that could form evidence in a future case.⁵

However, the definition of evidence is so broad that an opinion from a judicial officer seems to fall within its ambit. Accordingly, in determining whether Mr. Sheller met his burden regarding reasonable basis, the undersigned has considered all iterations of Boatmon. The undersigned has also considered other cases that found insufficient evidence regarding the theory that typical childhood vaccines can cause death in an infant. E.g., Jewell v. Sec'y of Health & Hum. Servs., No. 11-138V, 2016 WL 5404165, at *13 (Fed. Cl. Spec. Mstr. Aug. 29, 2016); Copenhaver v. Sec'y of Health & Hum. Servs., No. 13-1002V, 2016 WL 3456436, at *18 (Fed. Cl. Spec. Mstr. May 31, 2016), mot. for rev. denied, 129 Fed. Cl. 176 (2016); Lord v. Sec'y of Health & Hum. Servs., No. 12-255V, 2016 WL 806818, at *14 (Fed. Cl. Spec. Mstr. Feb. 9, 2016); Cozart v. Sec'y of Health

⁵ Ms. Toale appears to have started down this path but did not complete it to her destination.

& Hum. Servs., No. 00-590V, 2015 WL 6746616, at *13 (Fed. Cl. Spec. Mstr. Oct. 15, 2015), mot. for rev. denied, 126 Fed. Cl. 488 (2016).

C. Whether Reasonable Basis Supports the Claim Set Forth in the Petition

Having resolved two preliminary issues, the undersigned now turns to the crux of the pending motion—whether “there was a reasonable basis for the claim for which the petition was brought.” 42 U.S.C. § 300aa-15(e)(1). Here, the claim in Mr. Sheller’s petition is that Daniel’s death “was causally related to an adverse reaction” to the Pentacel and/or Prevnar vaccines. Pet., filed May 17, 2018, ¶ 9.

1. Standards for Adjudication

Petitioners who have not been awarded compensation (like Mr. Sheller here) are eligible for an award of attorneys’ fees and costs when “the petition was brought in good faith and there was a reasonable basis for the claim.” 42 U.S.C. § 300aa-15(e)(1). As the Federal Circuit has stated, “good faith” and “reasonable basis” are two separate elements that must be met for a petitioner to be eligible for attorneys’ fees and costs. Simmons, 875 F.3d at 635. Here, the Secretary has not raised a challenge to Mr. Sheller’s good faith. Thus, the disputed issue is reasonable basis.

In Cottingham v. Secretary of Health & Human Services, the Federal Circuit stated that the evidentiary burden for meeting the reasonable basis standard “is lower than the preponderant evidence standard.” 971 F.3d 1337, 1346 (Fed. Cir. 2020).⁶ Something “more than a mere scintilla” might establish the reasonable basis standard. Id. at 1346. Petitioners meet their evidentiary burden with “objective evidence.” Id. at 1344. In categorizing medical records as objective evidence, the Federal Circuit stated, “[m]edical records can support causation even where the records provide only circumstantial evidence of causation.” Id. at 1346. Finally, the Federal Circuit in Cottingham specified that “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. at 1347.

⁶ The Federal Circuit’s precedential opinion is referred to as Cottingham VII.

In its most recent opinion regarding the reasonable basis standard, the Federal Circuit stated that medical records, affidavits, and sworn testimony all constitute objective evidence that could support reasonable basis. James-Cornelius v. Sec’y of Health & Hum. Servs., 984 F.3d 1374, 1379-81. The Federal Circuit further clarified that “absence of an express medical opinion on causation is not necessarily dispositive of whether a claim has 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 1379 (citing Cottingham VII, 971 F.3d at 1346). These two most recent decisions guide the analysis regarding what types of evidence constitute objective evidence of reasonable basis, as originally articulated in Simmons, though the ultimate weighing of such evidence is left up to the special master.

One judge of the Court of Federal Claims has explained that in the context of vaccine injury, “causation is defined by the *Althen* prongs” and “[b]y extension, the *Althen* prongs may provide at least some definitional context to causation in a reasonable basis analysis.” Cottingham v. Sec’y of Health & Hum. Servs., 159 Fed. Cl. 328, 334-35 (2022), appeal docketed, No. 22-1737 (Fed. Cir. Apr. 28, 2022).⁷ Merely pointing to some evidence of a causal relationship between a vaccine and an injury is not necessarily sufficient to establish reasonable basis because evaluating the weight of objective evidence and whether it constitutes reasonable basis is a decision for the special master. Id. at 335 (citing Cottingham VII, 971 F.3d at 1346).

2. Evaluation of Evidence

Consistent with the approach taken in Cottingham XI, the method for assessing the evidence will follow the structure from Althen. However, the burden of proof is not the same.

a) Althen Prong One

The parties have focused much of their arguments on the question of whether reasonable basis supports the claim that childhood vaccines can cause an unexpected death in an infant. Mr. Sheller advances four points: Dr. Akbari’s letter, Dr. Miller’s email, various medical articles including the package insert, and the special master’s decision in Boatmon. The Secretary responds that taken collectively or individually, these are not enough. They are analyzed in turn.

⁷ This Cottingham opinion is referred to as Cottingham XI.

(1) Dr. Akbari's April 4, 2018 Letter

Although Mr. Sheller initially put forward Dr. Akbari's letter as support for a finding of reasonable basis for the claim set forth in the petition (see exhibit 11 ¶ 22), Mr. Sheller later acknowledged in oral argument that Dr. Akbari's opinion was not a causation opinion. Oral Arg. Tr. at 28-29. This description of Dr. Akbari's letter is correct—he did not offer an opinion that any vaccine caused Daniel's death.

Dr. Akbari recommended further testing. He summarized his assessment as “it is reasonable to conduct further inquiry including laboratory work.” Exhibit 5. An interest in obtaining more information differs from an opinion supporting causation.

Dr. Akbari has not presented any theory by which vaccines can cause an infant's death. At most, Dr. Akbari provides two potential reasons regarding the question of general causation: a decision by Dutch authorities to stop distribution of Prevnar and results of clinical trials.⁸

First, assessing the value of any activities by Dutch authorities is not possible because Mr. Sheller did not file any materials about it. Mr. Sheller repeated what Dr. Akbari said, but there is no direct record from Dutch officials. See, e.g., Pet'r's Supp., filed Aug. 24, 2008, at 8. While special masters must evaluate the entire record, special masters do not have to evaluate material that is not in the record.

Second, although not directly cited by Dr. Akbari, the source of information about clinical trials appears to be the package inserts. As part of the litigation over whether Mr. Sheller was eligible to receive attorneys' fees, Mr. Sheller filed the package inserts for Prevnar as exhibit 15. See Pet'r's Supp. at 9 n.8. In this context, Mr. Sheller states: “The most commonly reported serious adverse events were in the ‘Infections and infestations’ system organ class including bronchiolitis (0.9%, 1.1%), gastroenteritis, (0.9%, 0.9%), and pneumonia (0.9%, 0.5%) for Prevnar 13 and Prevnar respectively.” Id.: accord Pet'r's Reply, filed Sept. 30, 2020, at 5; Pet'r's Memo., filed Nov. 22, 2021, at 7-8. This quotation comes from page 6 of exhibit 15.

⁸ Evidence related to specific causation (Daniel's death) is discussed in section C(2)(b), below.

Two points temper the usefulness of these statistics. Preliminarily, saying that approximately one percent of infants and toddlers experienced bronchiolitis within one month after receiving Prevnar tells little, if anything, about whether Prevnar caused the bronchiolitis. See Grant v. Sec’y of Health & Hum. Servs., 956 F.2d 1144 (Fed. Cir. 1992). The package insert did not include bronchiolitis among “adverse drug reactions.” See exhibit 15 at 9.

More importantly, the package insert directly addresses the specific outcome in Daniel’s case, an infant’s death. “There were 3 (0.063%) deaths among Prevnar 13 recipients, and 1 (0.036%) death in Prevnar recipients, all as a result of sudden infant death syndrome (SIDS). These SIDS rates are consistent with published age specific background rates of SIDS from the year 2000.” Id. at 7.

Neither Dr. Akbari in his letter nor Mr. Sheller in his legal briefing has explained how clinical trials that did not detect an increased incidence of deaths following vaccination support the claim that the vaccination can cause a death.

Thus, to return to the start of this section about Dr. Akbari’s letter, Dr. Akbari did not opine that vaccinations can cause an infant’s death. It is not a causation opinion. As such, it is weaker than the evidence found insufficient to establish reasonable basis in Perreira v. Secretary of Health & Human Services.

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. 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 & Hum. 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 former 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 former Chief Special Master found that the Perreiras had a reasonable basis for filing their petition. Perreira v. Sec'y of Health & Hum. 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 former Chief Special Master explicitly found that a reasonable basis no longer existed after the expert submitted a report, noting that the expert's theory "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 former 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 & Hum. 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 & Hum. 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 & Hum. Servs., No. 13-336V, 2019 WL 3315326, at *4 (Fed. Cl. Spec. Mstr. June 24, 2019). The Federal Circuit interpreted 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.” Perreira, 33 F.3d at 1377.

When the holding of Perreira is applied to this case, Mr. Sheller's evidence falls short of crossing the reasonable basis threshold. In Perreira, the petitioners did not satisfy the reasonable basis standard with an expert's unsupported opinion that the DPT vaccine aggravated their daughter's seizures. Here, Mr. Sheller lacks an opinion from an expert that the vaccines harmed Daniel.

(2) Dr. Miller's Email

Dr. Miller's email is mostly about Daniel's autopsy with some discussion of other information about Daniel. Exhibit 20. Dr. Miller does not explicitly state that vaccines can cause an infant's death. He also does not explicitly propose a theory by which vaccines can cause an infant's death.

At best, Dr. Miller states: "I could write a report." Is an offer to write a report the same as a report for purposes of determining whether reasonable basis supports the claim set forth in the petition? The answer to that question is "No." An offer to write a report differs from a report.

In Chuisano, the petitioner represented to the court that she intended to retain an expert to write a report. Chuisano v. Sec'y of Health & Hum. Servs., No. 07-452V, 2013 WL 6234660, at *4 (Fed. Cl. Spec. Mstr. Oct. 25, 2013), mot. for rev. denied, 116 Fed. Cl. 276 (2014). However, after four motions for extensions of time to file such report, petitioner explained that her attorneys had reviewed a draft opinion from the expert and stated that they needed additional time. Id. at *5. However, the special master dismissed the case. Id. at *6. After the petitioner sought an award of attorneys' fees and costs, the Secretary objected. Id. The petitioner primarily argued that he relied upon the representations of the expert. Id. However, the special master explained that reasonable basis was not supported by "[t]he attorneys' beliefs and hopes about what evidence might be produced in the future" because beliefs and hope are not evidence. Id. at *19. After a motion for review was filed, the Court found that the special master's conclusion was "not 'arbitrary, capricious, an abuse of discretion, or not in accordance with law.'" Chuisano v. United States, 116 Fed. Cl. 276, 280 (2014) (internal citations omitted).

While the final opinion in Chuisano came from the Court of Federal Claims and, therefore, is not binding precedent, the Federal Circuit's opinion in Simmons reinforces the need for evidence. There, the Federal Circuit emphasized that reasonable basis is an objective test, one that is met with evidence. 875 F.3d at 635-36. Although Dr. Miller's letter is evidence, the letter is not an opinion that a

vaccine harmed Daniel and does not constitute more than a mere scintilla of evidence supporting vaccine-causation.

Indeed, Mr. Sheller stated that Dr. Miller’s work “led to the timely dismissal of Petitioner’s claim.” Pet’r’s Supp. at 16. Work by an expert retained by petitioners that leads to the dismissal of the claim would seem to constitute evidence that is contrary to the claims set forth in the petition. If the expert’s work supported the claims set forth in the petition, then, it would seem, that the claim would not be dismissed. Accordingly, Dr. Miller’s letter merits negligible, if any, weight in evaluating whether a reasonable basis supported the petition’s claim that vaccines caused Daniel’s death.

(3) Medical Articles

As discussed in the context of the Secretary’s motion to strike, Mr. Sheller discussed approximately 11 articles. See Pet’r’s Supp. Fees Mot., filed Aug. 24, 2020, at 9; Pet’r’s Resp. to Order, filed Nov. 22, 2021, at 6-8. The undersigned has reviewed those articles (exhibits 13-23). How those articles contribute to establishing reasonable basis for the claim that vaccines can cause a child’s death is not readily apparent. Some of these exhibits are in formats that rarely, if ever, are presented as evidence in the Vaccine Program. Even apart from the unusual style, the material tends to undermine a contention that vaccines can cause an infant’s death.

Within the group of articles in the record, the most reliable study is a study involving roughly 10,000 infants or toddlers that was performed to assess the safety of the DTaP-IPV/Hib vaccine. Exhibit 14 (John Hansen et al., Safety of DTaP-IPV/Hib Vaccine Administered Routinely to Infants and Toddlers, 34 Vaccine 4172 (2016)). Vaccinated two-month-old infants were monitored after given the first dose of the vaccine through six months after receiving a fourth dose at age 24 months. Id. Incidence rate ratios were calculated and revealed 166 comparisons with elevated incidence ratio rates. Id. However, the analyses performed “did not suggest any relationship with DTaP-IPV/Hib.” Id. The overall results of the study did not find any safety concerns with administering this vaccine and noted that the vaccine “was not associated with unexpected safety risks.” Id.

Another exhibit about vaccines and death in infants is exhibit 22 (Jane Woo Post-Approval Adverse Event Review: Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine (Pentacel) (2010)). Exhibit 22 is a PowerPoint presentation, which may or may not have been subject to peer-review.

One of the slides in Dr. Woo’s presentation on SIDS death reports states that “these reports do not raise any concerns about a causal relationship with Pentacel.” Id. at 12. Additionally, her presentation notes “[t]he evidence favors rejection of a causal relationship between exposure to multiple vaccines and SIDS.” Id. at 13. During a post-approval pediatric safety review of Pentacel, no new safety concerns were identified. Id. at 17.

Somewhat farther afield but still within the range of vaccines potentially associated with deaths is exhibit 19 (Sanofi Pasteur, Database Surveillance Safety Study of Pentacel Vaccine, NIH U.S. National Library of Medicine (Aug. 19, 2015), <https://clinicaltrials.gov/ct2/show/NCT00804284>). Mr. Sheller produced pages from a government website about clinical trials. The website shows that Sanofi sponsored a study with the purpose of examining the safety of the Pentacel vaccine and identifying any potential adverse related events as a result of the vaccine. Exhibit 19 (Sanofi study) at 1-2. The study ran from September 2008 to January 2015. Id. at 2. Exhibit 19 does not report any results. See id. However, the website lists one article as indexed to this clinical study.⁹ The Hansen researchers, as discussed above, did not detect any increased incidence of death after vaccination. Exhibit 14.

According to Mr. Sheller, these articles support a contention that vaccines can cause an infant’s death because researchers investigated the question. The fact that none of the studies linked vaccines as contributing to an increased incidence of death appears not to matter. But evidence that can most charitably be described as neutral (as opposed to downright negative) does not assist Mr. Sheller in meeting an affirmative obligation to demonstrate a reasonable basis for the petition’s claim that vaccines can cause an infant’s death.

Another series of articles discuss febrile seizures, not deaths in children after vaccination. Of this group, the most useful is a 2020 article that found a pneumococcal conjugate vaccine could be associated with an increased incidence of febrile seizures. Exhibit 23 (Meghan A. Baker et al., The Risk of Febrile Seizures Following Influenza and 13-Valent Pneumococcal Conjugate Vaccines, 38 *Vaccine* 2166 (2020)). A problem is that an article published in 2020 has questionable, if any, relevance to determining whether any evidence supported Mr.

⁹ The article is identified as “Hansen J, Timbol J, Lewis N, Pool V, Decker MD, Greenberg DP, Klein NP. Safety of DTaP-IPV/Hib vaccine administered routinely to infants and toddlers. *Vaccine*. 2016 Jul 29;34(35):4172-4179. doi:10.1016/j.vaccine.2016.06.062. Epub 2016 Jun 30.”

Sheller's petition considering that Mr. Sheller filed his case in 2018 and it was dismissed on January 13, 2020.

The Baker article is somewhat similar to a news account on a similar topic published in 2012. Exhibit 16 (Emma Hitt, Prevnar 13 Should Be Watched for Febrile Seizure Risk, FDA Panel Says, Medscape Medical News (Jan. 31, 2012), https://www.medscape.com/viewarticle/757814_print). To complete this series, a case report proposes that a child with febrile seizures whose death is induced by a seizure can appear consistent in manner with cases of sudden unexpected death in epilepsy. Exhibit 17 (Brian Dlouhy et al., Unexpected Death of a Child with Complex Febrile Seizures – Pathophysiology Similar to Sudden Unexpected Death in Epilepsy?, 8 *Frontiers Neurology* (2017)).

For these articles, an unacceptably wide gap between the medical records about Daniel and febrile seizures prevents their usefulness in supporting reasonable basis. Mr. Sheller has not identified any evidence that suggests Daniel suffered any seizure. Oral Arg. Tr. at 57. Ms. Toale's suggestion that he might have suffered a seizure is speculation from an attorney.

(4) Other Cases

Beyond the traditional types of evidence (statements from experts and articles subject to peer review), Mr. Sheller also maintains that the special master's decision in Boatmon supported the claim set forth in the petition. If opinions from judicial officers contribute to evaluating whether objective evidence supports a claim set forth in a petition, then Boatmon supports Mr. Sheller's position. In Boatmon, the special master found that petitioners were entitled to compensation in a SIDS case. Boatmon v. Sec'y of Health & Hum. Servs., No. 13-611V, 2017 WL 3432329, at *1, *43 (Fed. Cl. Spec. Mstr. July 10, 2017). In doing so, the special master credited opinions offered by Dr. Miller over Dr. McCusker, where Dr. Miller testified that the decedent died of SIDS and that vaccines substantially contributed to the death. Id. at *37, *39. As such, the special master ultimately concluded that the petitioners presented a vaccination causation theory that was reasonable and reliable. Id. at *38. If the special master's findings of fact had been upheld, then the petitioners would have been entitled to attorneys' fees and costs.

Boatmon's value, however, is complicated in two respects. To start, Boatmon's finding that vaccines can cause an infant's death is not consistent with findings of other special masters. This inconsistency seems to suggest that the outcome of Boatmon cannot be imported wholesale into other cases. Instead, those

other cases, including Mr. Sheller's case, would primarily (maybe exclusively) depend upon the evidence presented.

In addition to the special master's ruling in Boatmon being anomalous, another complication is that the special master's finding was overturned eventually. Of course, Mr. Sheller did not know when he filed his petition on May 17, 2018, the outcome of any appellate review. This chronology means that the Court of Federal Claims's reversal of the special master's decision on July 3, 2018, as well as the Federal Circuit's affirmance of the judgment denying compensation on November 7, 2019, cannot be held against Mr. Sheller in determining whether reasonable basis supported the petition when it was filed.

(5) Assessment

When considered as a whole, the record does not support a finding that Mr. Sheller has submitted sufficient evidence that vaccines can cause an infant's death. It bears repeating that the level of proof is not preponderance of the evidence.

At best, the presence of the special master's ruling in Boatmon made the claim that vaccines can cause an infant's death feasible. "Feasible," in this context, means that a petitioner might acquire evidence to support the claim. However, "feasibility" is not consistent with a jurisprudence in which the reasonable basis standard is met with evidence. Cottingham v. Sec'y of Health & Hum. Servs., No. 15-1291V, 2021 WL 6881248, at *21 (Fed. Cl. Spec. Mstr. Sept. 27, 2021) (noting that the Federal Circuit opinions in Cottingham VII and James-Cornelius did not set forth a "feasibility" standard), mot. for rev. denied, 159 Fed. Cl. 328 (2022).¹⁰

Apart from Boatmon, the evidence regarding the claim that childhood vaccines can cause an infant's death is lacking. Neither Dr. Akbari nor Dr. Miller presented developed opinions regarding causation. The medical articles, PowerPoint presentations, and news accounts either did not find an increased incidence of deaths after vaccinations or addressed a condition (seizures) that is not relevant. While Mr. Sheller might have a scintilla of evidence regarding prong one, a scintilla does not confer reasonable basis automatically. Cottingham VII, 971 F.3d at 1346 ("more than a mere scintilla but less than a preponderance of proof could provide sufficient grounds for a special master to find reasonable

¹⁰ The September 27, 2021 Cottingham decision is referred to as Cottingham X.

basis”); Cottingham XI, 159 Fed. Cl. at 333. Here for the reasons explained above, Mr. Shiller’s prong one evidence does not pass the reasonable basis threshold.

b) Althen Prong Two

As previously noted, Althen’s structure for establishing causation-in-fact at a preponderance of the evidence standard can be used as a structure for evaluating reasonable basis at a lower evidentiary standard. Accordingly, if Mr. Sheller had met the reasonable basis standard for prong one, then the next step would be to assess whether he met the reasonable basis standard regarding prong two. See Cottingham VII, 971 F.3d at 1345-46 (citing 42 U.S.C. § 300aa-11(c)(1) for the list of elements a petitioner must present, including as part of paragraph (C), a showing of causation); Cottingham XI, 159 Fed. Cl. at 334-35 (recognizing Althen as defining a test for causation-in-fact claims).

Mr. Sheller’s case illustrates why appellate guidance about the role Althen prong two plays (or does not play) in determining reasonable basis would be helpful. Through the work of Mr. Caldwell and Ms. Toale, Mr. Sheller has presented a least some evidence that could conceivably be stretched to support a finding that there is a reasonable basis on the prong one question—whether childhood vaccines can cause an infant’s death. For the reasons explained above, the undersigned finds that this case’s evidence, taken as a whole, does not pass the reasonable basis standard. But, once the analysis moves beyond the general question (can a vaccine cause an injury) to the specific question (did a vaccine cause this vaccinee’s injury), what is the inquiry for reasonable basis?

While the parties have focused much of their attention on the first Althen prong, the second Althen prong carries significance as well. In the context of adding depth to the Althen prongs, the Federal Circuit explained:

The second prong of the Althen III test is not without meaning. There may well be a circumstance where it is found that a vaccine can cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine. A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury.

Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d 1317, 1327 (Fed. Cir. 2006).¹¹

Here, the tenor of the parties’ briefing seems to suggest that if Mr. Sheller had a reasonable basis for asserting that childhood vaccines can cause an infant’s death, then he must automatically also have a reasonable basis for asserting that Daniel’s death was caused by a vaccination. However, as the passage from Capizzano illustrates, a persuasive (or reasonable) case regarding Althen prong one does not necessarily establish a persuasive (or reasonable) case regarding Althen prong two. Capizzano further identifies the evidence that is relevant in assessing Althen prong two: “medical records and medical opinions.” These two types of evidence match what the Vaccine Act says is essential in awarding compensation: “The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinions.” 42 U.S.C. § 300aa-13(a)(1) (emphasis added).

Cottingham VIII explained that in that case, because the vaccinee’s medical records did not suggest that a vaccination caused an injury, the argument that a reasonable basis supported the claim in the petition that a vaccination harmed the vaccinee necessarily implicated a medical opinion from a retained expert. Cottingham v. Sec’y of Health & Hum. Servs., No. 15-1291V, 2021 WL 347020, at *18-19 (Fed. Cl. Spec. Mstr. Jan. 7, 2021). However, the day after Cottingham VIII was issued, the Federal Circuit released its most recent precedential opinion regarding reasonable basis, James-Cornelius. There, the Federal Circuit declared an “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.” James-Cornelius, 984 F.3d at 1379. Because of this statement from the Federal Circuit, the Court of Federal Claims vacated the decision and remanded for additional analysis regarding reasonable basis. Cottingham v. Sec’y of Health & Hum. Servs., 154 Fed. Cl. 790 (2021).¹²

¹¹ Capizzano’s discussion of Althen prong two was in the context of a petitioner attempting to establish, by preponderance of evidence, that she was entitled to compensation. The preponderance of evidence standard, as mentioned above, is not the evidentiary standard for reasonable basis.

¹² This Cottingham opinion is referred to as Cottingham IX.

On remand, the (undersigned) special master attempted to comply with the mandate from the Court of Federal Claims as well as the Federal Circuit's direction in James-Cornelius and again found that there was not a reasonable basis for the claims set forth in the petition. Cottingham X, 2021 WL 6881248. Upon a motion for review, the Court of Federal Claims ruled that the finding of reasonable basis "was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Cottingham XI, 159 Fed. Cl. at 337. Thus, the Court of Federal Claims entered a judgment that the petitioner in Cottingham was not awarded attorneys' fees and costs. Ms. Cottingham has now appealed that judgment to the Federal Circuit and briefing has commenced.

It may be the case that the Federal Circuit's forthcoming opinion in Cottingham will provide more guidance to the participants in the Vaccine Program about whether Althen prong two is a factor in the reasonable basis analysis. Assuming that Althen prong two contributes to the reasonable basis analysis, an unresolved question, at least to the undersigned, is: can a petitioner satisfy the reasonable basis standard without a medical record explicitly suggesting that a vaccine could have caused an injury and without a medical opinion supporting causation?

This question is far from an academic point as the evidence about Daniel illustrates. With respect to medical records, except for some attempts to resuscitate him on the day of his death, Daniel did not receive any treatment for an injury that caused his death. The people providing medical services during Daniel's agonal process did not associate his recent vaccinations with his death. See exhibit 2.

In the autopsy performed on June 29, 2016, Daniel's body was "well-developed" and "well-nourished" upon external examination. Exhibit 3 at 17. However, the coroner did report "a 3/4 [inch] faint pink contusion over the right side of the forehead" as well as "a 1/4 [inch] faint pink contusion over the mid forehead." Id. at 18. The coroner concluded that Daniel's anatomic diagnosis was "[u]ndetermined" with "[n]o anatomical, histological, or toxicological cause." Id. at 21.

Thus, in explicit and direct terms, no medical record indicates that a vaccine might have caused Daniel's death. On the other hand, the medical records do present a chronology in which the vaccination preceded Daniel's demise. It might be the case that for purposes of establishing the reasonable basis of a claim in a petition that a vaccination caused a person's injury, a simple sequence of events in which a person is vaccinated and then develops an injury suffices. See Cottingham VII, 971 F.3d at 1346.

But this standard would be different from how causation is viewed in the entitlement stage. When determining whether petitioners have attempted to present preponderant evidence that a vaccination harmed them, a sequence of events is not the same as a statement of causation. Cedillo v. Sec’y of Health & Hum. Servs., 617 F.3d 1328, 1347-48 (2010); Grant v. Sec’y of Health & Hum. Servs., 956 F.2d 1144 (Fed. Cir. 1992).

Accordingly, Mr. Sheller has failed to present “medical records” that are sufficiently probative to establish the reasonable basis for the petition’s specific claim that the vaccinations caused Daniel’s death. A remaining option is that a “medical opinion” supports the assertion that the vaccinations caused Daniel’s death.

Here, too, the evidence is lacking. As discussed above, Dr. Akbari’s April 4, 2018 letter is not an opinion regarding causation. Oral Arg. Tr. at 28-29; see also exhibit 5.

Dr. Miller’s September 9, 2021 email also does not state that a vaccine caused Daniel’s death. Exhibit 20. An assessment of Dr. Miller’s email in the context of Althen prong two further illustrates why an offer to write a report differs from a report opining on causation. While Dr. Miller might have been able to present a theory how childhood vaccines might cause an infant’s death, Dr. Miller’s email does not persuasively identify a basis for opining that Daniel’s death was, more likely than not, due to a vaccination. See exhibit 20. This evidentiary gap weighs against finding a reasonable basis because a petitioner “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 VII, 971 F.3d at 1346 (emphasis added). Consequently, for the two types of evidence that Capizzano recognized as a relevant to Althen prong two (medical records and medical opinions), the evidence does not rise to a level that passes the threshold for reasonable basis.

Furthermore, whether the absence of a medical opinion affects the evaluation of whether a reasonable basis supports the claim that the vaccinations caused Daniel’s death is unclear in at least two respects. First, the Federal Circuit stated: “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. The term “necessarily” implies that in some cases, the lack of an express medical opinion might be dispositive. Cottingham X, 2021 WL 6881248 at *28. While the Federal Circuit has not yet had an opportunity to clarify when an absence of an express medical opinion is dispositive and when it is not dispositive,

it seems that Mr. Sheller's petition might present one instance in which the lack of an express medical opinion is particularly glaring. This is because until Boatmon, special masters had consistently found that the evidence did not preponderate in favor of finding that childhood vaccines can cause an infant's death. Thus, Mr. Sheller via his attorneys who are experienced in Vaccine Program cases was on notice that the claim set forth in his petition was one that was not typically approved. For Mr. Sheller to receive compensation for Daniel's death, it was likely that he would be required to produce some statement from an expert that linked the vaccinations to his son's death.

Second, the Federal Circuit further qualified its statement regarding an absence of medical opinion with the following clause: "especially when the case is in its early stages and counsel may not have had the opportunity to retain qualified experts." James-Cornelius, 984 F.3d at 1379. Here, as discussed in the procedural history, Mr. Sheller's two attorneys did have the opportunity to retain experts. Initially, Mr. Caldwell reached out to Dr. Akbari no later than March 2017, which was slightly more than one year before Mr. Caldwell submitted the petition on May 17, 2018. Then, after the petition had been pending for more than one year, Ms. Toale began conferring with Dr. Miller in July 2019. The actions of Mr. Caldwell and Ms. Toale are discussed only to demonstrate that by the time of its dismissal, Mr. Sheller's case had progressed beyond its "early stage." The actions (or inactions) of Mr. Caldwell and Ms. Toale are not otherwise relevant to the assessment of whether a reasonable basis supports the claim that the vaccinations caused Daniel's death. Simmons, 875 F.3d at 636.

In sum, even at a level of proof that is less demanding than the preponderance of the evidence standard, Mr. Sheller has failed to meet his burden to support the petition's specific claim that the vaccinations caused Daniel's death. In other words, the evidence regarding Althen prong two was not sufficient.

c) Althen Prong Three

The final Althen element for establishing causation-in-fact is a preponderant showing that "a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278. Again, to avoid any chance of misinterpretation, the Althen test is for causation and, therefore, provides only a structure for considering the evidence. The burden of proof for establishing reasonable basis is not as demanding.

Here, the analysis is not straightforward. At oral argument, the Secretary contended that the evidence for Althen prong three was limited to evidence

showing “that the vaccines did occur before [Daniel] died.” Oral Arg. Tr. at 70. The Secretary stated that he does not have any evidence about the timing of “when pulmonary edema might start before or after a vaccine”. Id.

However, contrary to the Secretary’s argument, some evidence provides information about a potentially proximate temporal relationship. For example, the Hansen investigators looked for various health problems within three days of a vaccination. Exhibit 14 at 4173. While the Secretary is correct that no expert explicitly endorsed that time in a statement filed in this case, whether an expert’s endorsement is essential is uncertain for the reasons just discussed. See James-Cornelius, 984 F.3d at 1379.

Furthermore, the events about Daniel are well-documented. Daniel received the Prevnar vaccine on June 21, 2016. Exhibit 1 at 2. He died on June 23, 2016. Exhibit 2 at 4. This two-day interval fits within the time that could be construed as a proximate temporal window.

Mr. Sheller’s success in establishing a reasonable basis for one of the three causation-in-fact prongs does not mean that he has established a reasonable basis for the other two prongs. A temporal sequence in which a vaccine precedes the injury “is necessary, but not sufficient” to establish reasonable basis. Chuisano, 116 Fed. Cl. at 287. For the reasons explained above, Mr. Sheller’s evidence regarding whether the vaccines can cause an infant’s death and his evidence regarding whether the vaccines did, in fact, cause Daniel’s death did not surpass the reasonable basis standard. Mr. Sheller, therefore, is not eligible for an award of attorneys’ fees and costs.

III. Conclusion

When petitioners in the Vaccine Program do not receive compensation, they are eligible for an award of attorneys’ fees and costs when a reasonable basis supports the claim set forth in the petition. Mr. Sheller’s petition claimed that childhood vaccines can cause an infant’s death and that the childhood vaccines did cause Daniel’s death. However, the objective evidence to support these assertions was lacking.

Accordingly, Mr. Sheller’s motion for an award of attorneys’ fees and costs is DENIED. The Clerk’s Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including deadlines, is available at the website for the Court of Federal Claims.

IT IS SO ORDERED.

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