

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 20-1420V

ANNA RICCI,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

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* **TO BE PUBLISHED**

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* Special Master Katherine E. Oler

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* Filed: June 2, 2022

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* Decision on Attorneys' Fees and Costs;
* Reasonable Basis; Human Papillomavirus
* ("HPV") Vaccine; Polycystic Ovary
* Syndrome ("PCOS")

Andrew D. Downing, Van Cott & Talamante, PLLC, Phoenix, AZ, for Petitioner
Darryl W. Wishard, U.S. Department of Justice, Washington, DC, for Respondent

DECISION DENYING PETITIONER'S MOTION FOR ATTORNEYS' FEES AND COSTS¹

On October 20, 2020, Anna Ricci ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*² (the "Vaccine Act" or "Program") alleging that she developed Polycystic Ovary Syndrome ("PCOS") from the Human Papillomavirus ("HPV") vaccination she received on December 21, 2017. Pet. at 3, ECF No. 1.

¹ This Decision will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). This means the Decision will be available to anyone with access to the internet. As provided in 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. To do so, each party may, within 14 days, request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, this Decision will be available to the public in its present form. *Id.*

² The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10-34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

On July 1, 2021, I issued a notice indicating that the statutory 240-day period for the special master's issuance of a decision in this case had expired. ECF No. 16. On August 2, 2021, Petitioner filed a Notice of Intent to Withdraw her petition pursuant to 42 U.S.C. § 300aa-21(b) and requested that an order be entered concluding proceedings. ECF No. 17. I issued an Order Concluding Proceedings on August 3, 2021. ECF No. 18.

Petitioner now moves for an award of attorneys' fees and costs. For the reasons discussed below, I find that the petition lacks reasonable basis; accordingly, Petitioner's motion is denied.

I. Procedural History

On October 20, 2020, Anna Ricci ("Petitioner") filed a petition for compensation alleging that she developed Polycystic Ovary Syndrome ("PCOS") from the Human Papillomavirus ("HPV") vaccination she received on December 21, 2017. Pet. at 1, ECF No. 1.

On November 2, 2020, Petitioner filed an affidavit (Ex. 1) and medical records (Exs. 2-5). ECF No. 6. Petitioner filed motions for additional time to file her PAR questionnaire, medical records, and statement of completion on November 2, 2020, December 2, 2020, and January 4, 2021 (ECF Nos. 7-8). Petitioner filed additional medical records on December 16, 2020 (Ex. 6), as well as the Gardasil package insert (Ex. 7). ECF No. 9. Petitioner filed the PAR questionnaire and a statement of completion on February 9, 2021. ECF Nos. 10-11.

This case was reassigned to my docket on April 19, 2021. ECF No. 13. I issued an Initial Order on that same day, directing Respondent to file a status report identifying any missing medical records and indicating how he would like to proceed. ECF No. 14.

On July 1, 2021, I issued a notice indicating that the statutory 240-day period for the special master's issuance of a decision in this case had expired. ECF No. 16. On the same date, Respondent filed a status report stating that he had completed his review of the record and requesting that I issue a deadline for his Rule 4(c) Report. ECF No. 17.

On August 2, 2021, Petitioner filed a Notice of Intent to Withdraw his Petition pursuant to 42 U.S.C. § 300aa-21(b) and requested that an order be entered concluding proceedings. ECF No. 17. I issued an Order Concluding Proceedings on August 3, 2021. ECF No. 18.

On September 7, 2021, Petitioner filed medical literature in support of her petition. Exs. 8-10, ECF Nos. 21-22. On the same date, Petitioner filed a motion for attorneys' fees and costs, requesting a total of \$7,896.00. Pet'r's Mot., ECF No. 23.

On September 14, 2021, Respondent filed a response to Petitioner's motion, arguing that the petition lacked both good faith and reasonable basis and therefore Petitioner's request for attorneys' fees and costs must be denied. Resp't's Resp. ECF No. 24.

On September 20, 2021, Petitioner filed a reply to Respondent's response, arguing that the petition possessed both good faith and reasonable basis and attorneys' fees and costs should be awarded. Pet'r's Reply, ECF No. 25. Petitioner also filed a supplemental motion for attorneys'

fees and costs on the same date, requesting an additional \$2,040.50 for a final requested total of \$9,936.50. ECF No. 26.

On April 1, 2022, Petitioner filed three recent decisions where special masters found that similarly-situated petitioners who exited the Program pursuant to the 240-day notice had filed their petitions in good faith and with a reasonable basis. ECF No. 29. On May 24, 2022, Petitioner filed another case where a special master found Petitioner's claim was brought in good faith and possessed a reasonable basis. ECF No. 30.³

This matter is now ripe for adjudication.

II. Petitioner's Relevant Medical History

On June 18, 2015, Petitioner visited Dr. Emanuel Cirenza for a well child exam. Ex. 3 at 9. She was diagnosed with allergic rhinitis. *Id.* at 10. Petitioner declined the HPV vaccination at this time. *Id.*

On July 12, 2016, Petitioner again visited Dr. Cirenza for a well child exam. Ex. 3 at 6. She again declined to receive an HPV vaccination. *Id.* at 8.

On March 10, 2017, Petitioner visited Nurse Practitioner Bernice Moeller-Bloom for a routine gynecological examination and to discuss birth control options prior to college. Ex. 3 at 16, Ex. 5 at 20. NP Moeller-Bloom stated that she had a "lengthy discussion [with Petitioner regarding] oral contraceptives related amenorrhea" and that Petitioner was "advised it is not an indicator of future fertility issues but delayed return of [] menses after [discontinuing] pills is more of a concern." Ex. 3 at 16. NP Moeller-Bloom stated that she "strongly encouraged [Petitioner] to re-consider Gardasil vaccinations as she is going off to college." Ex. 5 at 21. Petitioner also denied "fatigue, fever, weight gain, and unexplained weight loss" at this time. *Id.* at 84.

On June 20, 2017, Petitioner presented to Dr. Cirenza at Community Care Pediatrics for a well child exam. Ex. 3 at 2. It was noted that Petitioner had "not developed acne" at this time. *Id.* at 3. Petitioner indicated no concerns at this exam and Dr. Cirenza found none. *Id.* at 3-5. Petitioner received her first Gardasil vaccination on the same date. Ex. 2 at 1.

On July 10, 2017, Petitioner visited Dr. Sharon Kirkpatrick. Ex. 5 at 24. Under "Reason for Visit", Dr. Kirkpatrick noted that Petitioner felt as though her "body is slowly adjusting to [birth control], face and back broke out, [Petitioner] also has her period on appropriate days, [Petitioner was wondering why she is getting period with [birth control] she did not have a period last time she was on this [birth control]?" *Id.* Dr. Kirkpatrick noted that Petitioner's last period was approximately two weeks ago and her cycle was every 28 days on contraceptives. *Id.* at 25. Dr. Kirkpatrick further noted that "acne seems to have flared, now recovering slowly, still has acne on back. States 7 lb weight gain due to training for the half marathon she ran yesterday. Has gotten

³ I note that none of these cases involve allegations that the HPV vaccine caused petitioners to develop PCOS.

1 gardasil [sic] injection and is due for second one.” *Id.* Petitioner was advised to “observe for continued improvement in acne” and to “continue Gardasil [sic] protocol.” *Id.* at 27.

On August 21, 2017, Petitioner received the second dose of the Gardasil vaccine. Ex. 2 at 1. On December 21, 2017, Petitioner received her third dose of the Gardasil vaccine. *Id.*

On May 17, 2018, Petitioner presented to NP Moeller-Bloom for a routine gynecological examination. Ex. 3 at 15.⁴ NP Moeller-Bloom stated that the examination was “without abnormal findings.” *Id.* Petitioner’s symptoms included “persistent facial acne and increased hunger/wt gain on Sprintec.” Ex. 5 at 30. She stated that she had a “lengthy discussion with [Petitioner] about staying on same pill, changing back to LoEstrin or trying a new pill and [Petitioner] elects to try a new pill. [Petitioner] to observe for new symptoms and try to wait 3 months to see if its ok.” *Id.* at 32.

On October 16, 2018, Petitioner visited Dr. Marianne A. Mustafa at Saratoga Family Medicine for a new patient examination. Ex. 4 at 11. Dr. Mustafa noted that Petitioner was “a little concerned about her weight but she does follow a well-balanced diet and exercises by walking and using an elliptical.” *Id.* It was noted that Petitioner “denies neurologic symptoms” and “scored a one” on the depression screening.” *Id.* She also denied anxiety and depression. *Id.* Her mood was “normal” and a skin examination showed no abnormalities. *Id.* at 11-12.

On December 14, 2018, Petitioner called Saratoga OB/GYN to report that she “ha[d] not gotten [her] period since July when coming off the birth control (Sprintec).” Ex. 5 at 36. She also reported a “white pimpled area on [her] labia” and “cramping on and off since July but no bleeding.” *Id.* Nurse Paula Curro-Casey stated that Petitioner presented “with vaginitis symptoms including a vulvar lesion for the past 6 days.” *Id.* at 37. She also noted that Petitioner had a “history of secondary amenorrhea since coming off of OCP in July 2018.” *Id.* An examination revealed a vulvar lesion “on the right labia with an erythematous base.” *Id.* at 38. An HSV sample⁵ and Nu swab were taken. *Id.* at 39.

On December 20, 2018, Petitioner visited Saratoga OB/GYN for a follow up visit. Ex. 5 at 41. She was noted to have a “recent normal endocrine profile, but LH:FSH is 12.3:6.2 which is consistent with [PCOS].” *Id.* Petitioner was diagnosed with PCOS and irregular menses/secondary amenorrhea. Ex. 5 at 2. Petitioner stated that she would like to proceed with cyclic progesterone to manage her symptoms. *Id.* at 43.

On the same date, Petitioner underwent a pelvic ultrasound. Ex. 5 at 45. Petitioner’s endometrium appeared “thickened through the cervical canal.” *Id.* A “simple right ovarian cyst” was noted, and the left ovary showed “evidence of PCOS.” *Id.*

⁴ A different medical record from Dr. Sharon Kirkpatrick on the same date stated that Petitioner was experiencing “an issue with acne, and appetite.” Ex. 5 at 93. It is unclear whether this was part of the same appointment with NP Moeller-Bloom, or if Petitioner had a different appointment with Dr. Kirkpatrick on the same date.

⁵ This returned a negative result on the same date. Ex. 5 at 47.

On February 14, 2019, Petitioner visited psychiatrist Emily Tyre. Ex. 6 at 2. Petitioner stated that she “got in trouble in college in November and it continues to affect me every day. I am nervous and scared and sad all of the time.” *Id.* Dr. Tyre’s notes indicate that Petitioner “[w]as on an Honor Council at school for her Sorority and divulged some confidential information that subsequently got her kicked off of the Honor Council and on permanent probation until she graduates. Is terrified to make ‘any little mistake’ for fear of expulsion. Compulsive and ruminating thoughts that she may ‘mess up.’” *Id.* at 3. Dr. Tyre noted that Petitioner felt “persecuted by [her] school and [was] better about her maltreatment.” *Id.* Petitioner saw Dr. Tyre for the same reasons on March 7, 2019.

No other pertinent medical records have been filed.

III. Petitioner’s Affidavit

Petitioner averred that she did not notice any adverse effects following receipt of her first two Gardasil vaccinations on June 20, 2017, and August 21, 2017. Ex. 1 at 1. She received her third dose of the vaccination on December 21, 2017. *Id.* Petitioner stated that “[t]wo weeks after I got the third shot, my face broke out in acne like never before. Shortly thereafter, I started to develop brain fog, which I called my gynecologist about thinking it had to do with my birth control that I was on at the time. I developed heightened depression and anxiety symptoms, and started gaining lots of weight.” *Id.*

Petitioner stated that in December 2018, she was diagnosed with PCOS. Ex. 1 at 1. She stated that “instead of taking more pills, I opted to heal myself naturally.” *Id.* Petitioner further indicated that she continues to suffer from PCOS, acne, depression/anxiety, weight gain, and brain fog as a result of the HPV vaccine she received. *Id.*

IV. Medical Literature

Petitioner filed the following medical literature, not including the Gardasil package insert (which was filed as Ex. 7). Petitioner additionally filed the complaint by Ms. Sahara Walker in *Sahara Walker v. Merck & Co, Inc.*⁶

A. Mobeen et al., *Polycystic Ovary Syndrome May be an Autoimmune Disorder*, SCIENTIFICA (CAIRO) 4071735 (2016) (Ex. 8)

This paper discusses the possible classification of PCOS as an autoimmune disorder. Ex. 8 at 1 (hereinafter “Mobeen”). The authors state that “PCOS is essentially a hormonal disorder and is buttressed by insulin resistance and hyperandrogenism.” *Id.* at 4. They note that “the pathophysiologic linkage between PCOS and type 1 [diabetes mellitus] has been declared an autoimmune phenomenon but it is still not established.” *Id.* The authors conclude that “[t]here is an association between PCOS and autoimmune diseases such as ANA and anti-TPO that have been

⁶ Given that the complaint is a subjective recitation from an attorney alleging disputed facts in a different case, I have afforded it little weight in my analysis. And, given that the complaint makes no mention of PCOS, its probative value is low.

documented in systemic lupus erythematosus and Hashimoto thyroiditis, respectively, but “[f]urther studies are needed at [the] genetic and molecular level to establish the contribution of autoimmunity in PCOS.” *Id.*

B. Hefler-Frischmuth et al., *Serologic Markers of Autoimmunity in Women with Polycystic Ovary Syndrome*, 93 FERTILITY AND STERILITY 7, 2291-94 (2010) (Ex. 9)

This paper attempted to determine the role of autoimmune processes in women with PCOS. Ex. 9 at 2291 (hereinafter “Hefler-Frischmuth”). The authors noted that “autoimmune mechanisms have been hypothesized to be involved in various ovarian pathologies such as...PCOS.” *Id.* They stated that “[t]he exact role of autoimmune processes such as those described remains controversial in women with the PCOS” and that the aim of the study in this paper “was to contribute further data on autoimmunologic processes and to elucidate potential mechanisms for their interrelation in PCOS.” *Id.* at 2291-92.

In their discussion, the authors stated that:

Processes of autoimmunity have been shown to be associated with numerous conditions and diseases such as thyroid disease, diabetes mellitus, rheumatoid arthritis, SS, and SLE. In the field of obstetrics and gynecology, preeclampsia, recurrent miscarriage, endometriosis, fibroids, several malignant tumors, and ovarian diseases such as premature ovarian failure (POF) have been shown to be associated with autoimmunologic processes. Regarding PCOS, studies on autoimmunity yielded conflicting results.

Hefler-Frischmuth at 2293 (omitting internal citations). In analyzing the data, the authors noted that “a role for autoimmunologic processes might be present in the pathogenesis of PCOS” but that “the evaluation of the exact pathways of these antibodies remains to be determined.” *Id.* at 2294. Ultimately, the authors concluded that “Our study shows that serologic parameters of autoimmunity (i.e., antihistone and anti-dsDNA antibodies) are elevated in women with PCOS. A role of autoimmunologic processes in PCOS can be suspected.” *Id.*

C. Little & Ward, *Adolescent Premature Ovarian Insufficiency Following Human Papillomavirus Vaccination: A Case Series Seen in General Practice*, J. INVESTIGATIVE MED. HIGH IMPACT CASE REPORTS 1, 1-12 (2014)

This paper discussed three women who developed premature ovarian insufficiency (POI) following receipt of the HPV vaccine. Ex. 10 at 1 (hereinafter “Little & Ward”). The authors concluded that “it is not known whether idiopathic POI developing progressively in young teens following HPV4 is related to this vaccination.” *Id.* at 10. They stated that “case reports do not and cannot establish causation” and that “further studies are required to make any claims of ovary complications.” *Id.*

No other medical literature has been filed.

V. Parties' Arguments

Petitioner argued in her motion that a reasonable basis existed for submitting her petition in the Program. Pet'r's Mot., ECF No. 23 at 2. In her motion, she stated that "Petitioner's medical chart supports the causal connection between vaccination and the injury claimed." The motion further stated that

Two weeks after the third shot, her face broke out in acne. Shortly thereafter, she started to develop brain fog. She called her gynecologist, thinking it had to do with her birth control medication. She developed heightened depression and anxiety symptoms, and started gaining lots of weight. She shrugged these things off, thinking that they all were unrelated, but when she went off the birth control pill in June 2018 and did not get her period back for months, she knew something was really wrong.

Pet'r's Mot. at 3, *citing* Pet'r's Affidavit, Ex. 1 at 1. Petitioner's Motion further indicated that a reasonable basis exists.

Given Petitioner's diagnosis in her medical chart, the onset of symptoms in a temporal timeframe consistent with other autoimmune presentations (two weeks postvaccination), and the fact that peer-reviewed medical literature describes the condition as an autoimmune process, it is reasonable to conclude that Petitioner's HPV vaccination was the catalyst for her disease.

Pet'r's Mot. at 5.

In his Response, Respondent stated that the "petitioner lacks a reasonable basis for her claim and did not file or maintain the claim in good faith." Resp't's Resp., ECF No. 24 at 1. Respondent further stated that "Petitioner's medical records and exhibits provide evidence that her PCOS likely began sometime before her June 20, 2017" HPV vaccination. *Id.* at 8.

Respondent argued that the petition lacks good faith because Petitioner "filed the petition solely as a step towards her ultimate goal of bringing a cause of action against Merck directly." Resp't's Rep. at 11. Respondent argued that "by...asking for reimbursement of her attorneys' fees and costs...petitioner is effectively asking the manufacturers, via the Vaccine Trust Fund, to subsidize her civil suit against Merck, all while depriving Merck of the *quid quo pro* [sic] of a decision and judgment resolving her claim on the merits in the Vaccine Program." *Id.*

Respondent argued that the petition also lacks reasonable basis. Resp't's Rep. at 11. Respondent stated that the evidence contained in the medical records "shows that petitioner likely had PCOS before her first dose of HPV vaccine on June 20, 2017." *Id.* at 12. Furthermore, Respondent argued that Petitioner's affidavit does not confer a reasonable basis for her petition and that there is no documentation in the medical records of symptoms such as brain fog. *Id.* Respondent argued that Petitioner failed to provide a reliable medical theory causally linking the HPV vaccine to her alleged injury in general, failed to show that PCOS is likely an autoimmune

disease, and failed to show that the HPV vaccine was the reason for her alleged injury specifically in this case. *Id.* at 13.

In her reply brief, Petitioner stated that “in order to join the Merck litigation, victims are statutorily compelled to first submit a claim to the Vaccine Program.” Pet’r’s Reply, ECF No. 25 at 6. Accordingly, she argued Respondent’s public policy argument that the petition was not filed in good faith must fail. Petitioner further stated that she had filed an affidavit under oath in which she stated her belief that she was injured by the Gardasil vaccine and therefore good faith for filing the petition existed. *Id.* at 7.

Petitioner also reasserted that she had a reasonable basis to file her claim. Pet’r’s Reply at 8. Petitioner stated that an expert or treating doctor’s opinion on causation is not required to establish reasonable basis. *Id.* at 8-9, citing *James-Cornelius v. Sec’y of Health & Hum. Servs.*, 984 F.3d 1374, 1382 (Fed. Cir. 2021) (holding that “absence of an express medical opinion on causation is not necessarily dispositive of whether a claim has a reasonable basis...”). Petitioner asserted that the statements made in her affidavit are “extremely probative” and that these statements constitute objective evidence supporting reasonable basis. *Id.* at 9.

Petitioner further stated that PCOS “is, in fact, autoimmune” and that “Ovarian insufficiency/dysfunction has previously been linked to Gardasil.” Pet’r’s Reply at 11 (omitting internal citations).

Petitioner concluded her reply by stating that “given Petitioner’s diagnosis in her medical chart, the onset of symptoms in a temporal timeframe consistent with other autoimmune presentations (two weeks post-vaccination) and the fact that peer-reviewed medical literature describes the condition as an autoimmune process, it is reasonable to conclude that Petitioner’s HPV vaccination was the catalyst for her disease.” Pet’r’s Reply at 11.

VI. Legal Standard

A. Good Faith

The good faith requirement is met through a subjective inquiry. *Di Roma v. Sec’y of Health & Hum. Servs.*, No. 90-3277V, 1993 WL 496981, at *1 (Fed. Cl. Spec. Mstr. Nov. 18, 1993). Such a requirement is a “subjective standard that focuses upon whether [P]etitioner honestly believed he had a legitimate claim for compensation.” *Turner v. Sec’y of Health & Hum. Servs.*, No. 99-544V, 2007 WL 4410030, at *5 (Fed. Cl. Spec. Mstr. Nov. 30, 2007). Without evidence of bad faith, “petitioners are entitled to a presumption of good faith.” *Grice v. Sec’y of Health & Hum. Servs.*, 36 Fed. Cl. 114, 121 (1996). Thus, so long as Petitioner had an honest belief that her claim could succeed, the good faith requirement is satisfied. *See Riley v. Sec’y of Health & Hum. Servs.*, No. 09-276V, 2011 WL 2036976, at *2 (Fed. Cl. Spec. Mstr. Apr. 29, 2011) (citing *Di Roma*, 1993 WL 496981, at *1); *Turner*, 2007 WL 4410030, at *5.

B. Reasonable Basis

Unlike the good-faith inquiry, an analysis of reasonable basis requires more than just a

petitioner's belief in his claim. *Turner v. Sec'y of Health & Hum. Servs.*, No. 99-544V, 2007 WL 4410030, at *6-7 (Fed. Cl. Spec. Mstr. Nov. 30, 2007). Instead, the claim must be supported by objective evidence. *Simmons v. Sec'y of Health & Hum. Servs.*, 875 F.3d 632, 636 (Fed. Cir. 2017).

While the statute does not define the quantum of proof needed to establish reasonable basis, it is "something less than the preponderant evidence ultimately required to prevail on one's vaccine-injury claim." *Chuisano v. United States*, 116 Fed. Cl. 276, 283 (2014). The Court of Federal Claims affirmed in *Chuisano* that "[a]t the most basic level, a petitioner who submits no evidence would not be found to have reasonable basis..." *Id.* at 286. The Court in *Chuisano* found that a petition which relies on temporal proximity and a petitioner's affidavit is not sufficient to establish reasonable basis. *Id.* at 290; *see also Turpin v. Sec'y Health & Hum. Servs.*, No. 99-564V, 2005 WL 1026714, *2 (Fed. Cl. Spec. Mstr. Feb. 10, 2005) (finding no reasonable basis when petitioner submitted an affidavit and no other records); *Brown v. Sec'y Health & Hum. Servs.*, No. 99-539V, 2005 WL 1026713, *2 (Fed. Cl. Spec. Mstr. Mar. 11, 2005) (finding no reasonable basis when petitioner presented only e-mails between her and her attorney). The Federal Circuit has affirmed 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." *Cottingham v. Sec'y of Health & Hum. Servs.*, 971 F.3d 1337, 1346 (Fed. Cir. Aug. 19, 2020) (finding Petitioner submitted objective evidence supporting causation when she submitted medical records and a vaccine package insert); *see also James-Cornelius*, 984 F.3d at 1380 (finding that "the lack of an express medical opinion on causation did not by itself negate the claim's reasonable basis.").

Temporal proximity between vaccination and onset of symptoms is a necessary component in establishing causation in non-Table cases, but without more, temporal proximity alone "fails to establish a reasonable basis for a vaccine claim." *Chuisano*, 116 Fed. Cl. at 291.

"[I]n deciding reasonable basis the [s]pecial [m]aster needs to focus on the requirements for a petition under the Vaccine Act to determine if the elements have been asserted with sufficient evidence to make a feasible claim for recovery." *Santacroce v. Sec'y of Health & Hum. Servs.*, No. 15-555V, 2018 WL 405121, at *7 (Fed. Cl. Jan. 5, 2018). Special masters cannot award compensation "based on the claims of petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1).

When determining if a reasonable basis exists, many special masters and judges consider a myriad of factors. The factors to be considered may include "the factual basis of the claim, the medical and scientific support for the claim, the novelty of the vaccine, and the novelty of the theory of causation." *Amankwaa*, 138 Fed. Cl. at 289. This approach allows the special master to look at each application for attorneys' fees and costs on a case-by-case basis. *Hamrick v. Sec'y of Health & Hum. Servs.*, No. 99-683V, 2007 WL 4793152, at *4 (Fed. Cl. Spec. Mstr. Nov. 19, 2007).

C. Elements of a *prima facie* Case

The Vaccine Act requires petitioners to provide objective evidence of five elements to make out a *prima facie* case for compensation:

1. The Petitioner received a vaccine set forth in the Vaccine Injury Table;
2. The Petitioner received a vaccine in the United States or outside of the United States under some special circumstances;
3. The Petitioner's injuries or death were caused by the vaccine (either by showing that the injury was one listed on the Vaccine Injury Table, or by making out a prima facie case of causation-in-fact), or the vaccine significantly aggravated a pre-existing injury;
4. The Petitioner experienced the residual effects of the injury for more than six months, died, or required an in-patient hospitalization with surgical intervention; and
5. The Petitioner has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death.

42 U.S.C. § 300aa-11(c)(1)(A)-(E). In order to establish reasonable basis, a Petitioner must present objective evidence as to each of these elements. *Cottingham*, 971 F.3d at 1344, 1345-46.

VII. Discussion

A. Good Faith

Respondent contests that the petition was filed in good faith, arguing that a petition is not filed in good faith if it is made solely with the purpose of later exiting the Vaccine Program in order to file a civil suit against the vaccine manufacturer. Resp't's Resp. at 10.

Petitioner submitted four cases to support her position that the petition was filed in good faith. *Hoover v. Sec'y of Health & Hum. Servs.*, No. 20-1394V, 2021 U.S. Claims LEXIS 2566, (Fed. Cl. Spec. Mstr. Nov. 1, 2021); *Bob v. Sec'y of Health & Hum. Servs.*, No. 20-931V, 2022 U.S. Claims LEXIS 125 (Fed. Cl. Spec. Mstr. Jan. 25, 2022); *Nyboer v. Sec'y of Health & Hum. Servs.*, No. 21-1010V, 2022 U.S. Claims LEXIS 204 (Fed. Cl. Spec. Mstr. Jan. 27, 2022); *Wingter v. Sec'y of Health & Hum. Servs.*, No. 20-1408V, Dkt. No. 25 (May 17, 2022) (filed as ECF No. 30, Ex. D).⁷ The issue of good faith has also been recently addressed in *Thomas v. Sec'y of Health & Hum. Servs.*, No. 20-886V, 2021 U.S. Claims LEXIS 1103 (Fed. Cl. Spec. Mstr. May 17, 2021). In each of these decisions, the Special Masters explained that (1) the Vaccine Act "specifically creates a mechanism for petitioners to withdraw from the program and pursue civil litigation" and (2) complying with the statute to withdraw a petition specifically to pursue civil litigation is not inconsistent with the Vaccine Act. *Nyboer*, 2022 U.S. Claims LEXIS at *19 (omitting internal citations).

I agree with my colleagues. The Vaccine Act's statutory scheme is designed to provide petitioners who are injured by a covered vaccine with an award "quickly" and with "generosity". *Lowry ex rel. Lowry v. Sec'y of Health & Hum. Servs.*, 189 F.3d 1378, 1381 (Fed. Cir. 1999). In exchange, one of the procedural components of the Act "requires a claimant to first seek redress

⁷ This decision is not yet publicly available.

in the [Vaccine Court] before attempting to obtain relief in a court of general jurisdiction.” *Romero v. Wyeth*, 145 Fed. Appx. 962, 964 (Fifth Cir. 2005). The Vaccine Act is silent as to petitioners’ mindset concerning how they would like to ultimately resolve their claim; it only mandates that they *first* file a claim in this Court. *See Thomas*, 2021 U.S. Claims LEXIS 1103 at *14. The Vaccine Act explicitly contemplates that petitioners may wish to pursue a civil action after 240 days. 42 U.S.C. § 300aa-11(a)(2)(A)(ii). The only requirement petitioners must meet to establish good faith is an honest belief that they were injured by the vaccine. *Riley*, 2011 WL 2036976, at *2. Here, Petitioner has filed an affidavit averring that she suffered, among other injuries, brain fog, weight gain, facial acne, and PCOS after the HPV vaccine she received on December 21, 2017. Ex. 1 at 1. I find that this statement satisfies the subjective standard for good faith.

B. Reasonable Basis

Petitioner has submitted some objective evidence concerning the following points: 1) Petitioner received her third HPV vaccine on December 21, 2017; 2) she developed worsening acne approximately two weeks after vaccination, followed by brain fog, depression and anxiety and weight gain;⁸ 3) several of these signs and symptoms are consistent with Polycystic Ovary Syndrome; 4) Petitioner was diagnosed with Polycystic Ovary Syndrome; 5) Polycystic Ovary Syndrome may be an autoimmune disease; and 6) the HPV vaccine can cause some autoimmune diseases. An examination of Petitioner’s proffered evidence demonstrates that she has not provided more than a mere scintilla of objective evidence supporting a causal relationship between the administration of the HPV vaccine and her development of Polycystic Ovary Syndrome. *Cottingham*, 971 F.3d 1337, 1346 (stating that “[b]ecause causation is a necessary element of a petition, [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.”). Because of this, she has not provided sufficient evidence to establish that her petition possesses a reasonable basis.

Petitioner’s medical records do not link her development of PCOS to the HPV vaccine. Further, Petitioner has not submitted an expert report linking her development of PCOS to her vaccination. However, even absent medical opinion evidence, Petitioner can still establish reasonable basis. *James-Cornelius*, 984 F.3d at 1380.

In examining the submitted medical literature, I find that Petitioner has not provided more than a mere scintilla of evidence linking HPV vaccination to the development of PCOS. Petitioner’s medical literature includes the Gardasil package insert and three medical articles. The package insert states that “2.2% of Gardasil 9 and 3.3% of Gardasil recipients reported new medical conditions potentially indicative of systemic autoimmune disorders, which were similar to rates reported following Gardasil, AAHS control, or saline placebo in historical clinical trials.” Ex. 7 at 8. The package insert additionally states that autoimmune hemolytic anemia and

⁸ Although the contemporaneous medical records do not document that these signs and symptoms took place when Petitioner alleged they did, Petitioner’s affidavit does provide some evidence that she suffered from these conditions close-in-time to her third HPV vaccine. I note that Petitioner’s development of symptoms several weeks after her third HPV vaccine, by itself, is not sufficient to establish reasonable basis. *Chuisano*, 116 Fed. Cl. at 290.

autoimmune diseases have been spontaneously reported as an adverse experiences for Gardasil. *Id.* at 9. The package insert does not state that Polycystic Ovary Syndrome has been a reported event after Gardasil vaccine. Although Petitioner’s affidavit indicates that she began experiencing worsening acne approximately two weeks after vaccination, followed by brain fog, depression and anxiety and weight gain, these symptoms are not listed as adverse reactions in the Gardasil package insert. *See generally id.*

The Mobeen and Hefler-Frischmuth articles discuss PCOS and hypothesize that it may be an autoimmune condition.⁹ The Mobeen article (titled *Polycystic Ovary Syndrome May be an Autoimmune Disorder*) states that “[f]urther studies are needed at [the] genetic and molecular level to establish the contribution of autoimmunity in PCOS.” Mobeen at 4. Similarly, the Hefler-Frischmuth article states that “autoimmune mechanisms have been hypothesized to be involved in various ovarian pathologies such as...PCOS.” Hefler-Frischmuth at 2291. The authors conclude that “[a] role of autoimmunologic processes in PCOS can be suspected.” *Id.* at 2293. Neither Mobeen nor Hefler-Frischmuth discuss the HPV vaccine.

The Little & Ward article is also unhelpful to Petitioner. That article discusses the development of premature ovarian insufficiency (POI) in three women following receipt of the HPV vaccination. Little & Ward at 1. But Petitioner here does not allege POI, and instead alleges that she suffers from PCOS. Petitioner has presented no evidence establishing a relationship between PCOS and POI. I therefore decline to find case reports that describe POI after HPV vaccination confer reasonable basis on a petition alleging HPV vaccination-induced PCOS.

Petitioner asks me to find that because HPV vaccination may cause *some* autoimmune disorders, it could cause some other, entirely different autoimmune disorder. Petitioner further asks me to find that, because PCOS may be an autoimmune disease, the HPV vaccine can cause PCOS. Petitioner ultimately asks me to conclude that these facts together with Petitioner’s PCOS diagnosis and the onset of her symptoms close-in-time to vaccination means there is evidence of a causal relationship between the HPV vaccine she received and her diagnosis of PCOS.

Petitioner’s burden is to provide more than a mere scintilla of evidence in support of her claim. In discussing the meaning of more than a mere scintilla of evidence, the court in *Cottingham* cited to *Sedar v. Reston Town Ctr. Prop., LLC* where the Fourth Circuit defined the term as “evidence beyond speculation that provides a sufficient basis for a reasonable inference of causation.” 988 F.3d 756, 761, n.3 (4th Cir. 2021). I do not find the evidence presented in this case establishes “a sufficient basis for a reasonable inference of causation” between the HPV vaccine and PCOS. Accordingly, I do not find that Petitioner has presented more than a mere scintilla of evidence that a causal relationship between HPV vaccination and PCOS exists, and thus she has not established that her claim possesses a reasonable basis.

⁹ These articles do not demonstrate that PCOS is an autoimmune disease, but articulate a hypothesis that it may be autoimmune in nature. Even assuming these articles definitively established that PCOS is autoimmune, this point would similarly not confer reasonable basis. Certainly, if a disease is not autoimmune, a petitioner’s ability to establish reasonable basis is reduced. However, a disease’s status as an autoimmune condition does not speak with particularity as to whether a causal relationship between the vaccine and the disease exists, and thus does not confer reasonable basis.

VIII. Conclusion

Accordingly, in the exercise of the discretion afforded to me in determining the propriety of fee and cost awards, and based on the foregoing, I **DENY** Petitioner's application for attorneys' fees and costs.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this decision.¹⁰

IT IS SO ORDERED.

s/ Katherine E. Oler

Katherine E. Oler
Special Master

¹⁰ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.