In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: August 31, 2022

CAMILA DO ESPIRITO SANTO,	*	No. 18-1725v
Petitioner,	*	Special Master Sanders
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on the Record; Entitlement Decision; Influenza ("Flu") Vaccine; Measles Mumps Rubella ("MMR") Vaccine; Preeclampsia; Missed Abortion
Respondent.	*	

John F. McHugh, Law Office of John McHugh, New York, N.Y., for Petitioner
Lynn C. Schlie, United States Department of Justice, Washington, D.C., for Respondent

DECISION ON ENTITLEMENT[1]

On November 5, 2018, Camila Do Espirito Santo ("Petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program ("Program" or "Vaccine Program").[2] Petitioner alleges that she received the measles mumps rubella ("MMR") and influenza ("flu") vaccinations on October 15, 2016, and that these vaccines resulted in "injuries affecting the health of her fertility, such as [the] death of [her] in utero child (missed abortion), and subsequent severe preeclampsia."[3] Pet. at 1, ECF No. 1.

Respondent filed a motion for a ruling on the record dismissing Petitioner's claim on August 30, 2021. Resp't's Mot., ECF No. 57. Petitioner filed a response on December 9, 2021. Pet'r's Resp., ECF No. 61. Respondent did not file a reply. This matter is now ripe for

[1] This Decision shall 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 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to redact medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted Decision. If, upon review, I agree that the identified material fits within the requirements of that provision, such material will be withheld from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99–660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

[3] Preeclampsia is "a complication of pregnancy characterized by hypertension, edema, and/or proteinuria; when convulsions and coma are associated[.]" *Dorland's Illustrated Medical Dictionary* 1, 1509 (32nd ed. 2012) [hereinafter "*Dorland's*"].

consideration. For the reasons stated below, I **GRANT** Respondent's motion and Petitioner's case is hereby **DISMISSED**.

I. Procedural History

Petitioner filed her petition for compensation, *pro se*, on November 5, 2018. *See* Pet. On that date, Petitioner also filed her green card documentation and several medical records. Pet'r's Exs. 1–10, ECF Nos. 1-3–1-12. Petitioner filed additional medical records and a statement of completion on December 26, 2018. Pet'r's Ex. 12, ECF Nos. 9–10. On February 21, 2019, Petitioner filed additional medical records, medical literature, and two affidavits. Pet'r's Exs. 18, 40, 69–131, 133, ECF Nos. 11-1–11-68.

The same day, Petitioner filed a motion to change the case caption to include an action "on behalf of her unborn child." ECF No. 13. On March 11, 2019, Respondent filed his response to Petitioner's motion. Resp't's Resp., ECF No. 15. On March 18, 2019, Petitioner submitted a reply to Respondent's response. Pet'r's Reply, ECF No. 16. I denied Petitioner's motion on July 25, 2019, and found Petitioner "may not assert more than one claim per petition . . . [or] on behalf of a petitioner who was not born alive." Order at 3, ECF No. 18. Instead, I noted Petitioner must assert one claim on her behalf for her miscarriage and subsequent severe preeclampsia and one claim on behalf of any child born alive for his or her injury. *Id.*

Respondent noted in a status report filed on August 26, 2019, that several medical records were missing, including Petitioner's pre-vaccination records. ECF No. 20. Petitioner filed additional records on September 26, 2019, and a statement of completion. Pet'r's Exs. 135–137, ECF Nos. 22–23. Petitioner filed a motion to issue a subpoena for outstanding medical records on December 2, 2019, which I granted on December 5, 2019. ECF Nos. 27, 29.

Respondent then filed his Rule 4(c) report on December 30, 2019. Resp't's Report, ECF No. 30. In his report, Respondent stated that Petitioner has not "provided a medical expert report in support of her claim," and her claim should be denied. *Id.* at 1. Petitioner responded to Respondent's report on February 3, 2020, with a status report regarding her submitted evidence, including "vaccine injury compensation data," and medical literature. Pet'r's Exs. 142–148, ECF Nos. 32-1–32-7.

On July 24, 2020, I ordered Petitioner to file an expert report by no later than September 21, 2020. ECF No. 35. I extended the deadline on several occasions through November 23, 2020. *See* ECF Nos. 37, 40, 42. On November 13, 2020, Petitioner filed a motion to substitute counsel. ECF No. 43. I granted the motion, and Mr. Howard Gold began his representation of Petitioner on November 19, 2020. ECF No. 44. On November 19, 2020, Petitioner requested an additional extension of time, until January 22, 2021, to obtain and file an expert report. ECF No. 46. After a fifth extension of time, Petitioner filed her expert report from Dr. Leslie Hansen Lindner on March 12, 2021, along with a status report. Pet'r's Ex. A, ECF Nos. 48–49. After a review of Petitioner's expert report, I scheduled a status conference with the parties that was held on March 18, 2021. Min. Entry, docketed Mar. 18, 2021. During the conference, Petitioner's counsel indicated his intention to withdraw from the claim. *See* ECF No. 50. On March 28, 2021, Petitioner filed a motion for attorneys' fees on behalf of Mr. Gold indicating that he had withdrawn from the case

because it "became clear to [c]ounsel that upon the filing of the expert report from Dr. Hansen Lindner that reasonable basis to continue with this claim would no longer exist." Pet'r's Mot. at 2, ECF No. 51. On May 4, 2021, Mr. John McHugh substituted in as counsel for Petitioner. ECF No. 54. I awarded Petitioner a final opportunity, until June 21, 2021, to obtain and file an expert report in compliance with my July 24, 2020 Order. ECF No. 55. On June 21, 2021, Petitioner filed a status report wherein she acknowledged that the expert report she filed on March 12, 2021, was inadequate. ECF No. 56 at 1. She further stated that she had "been unable to locate an expert in the field in the time allotted," and she is "determined to proceed with the same expert[]" and her claim as it is. *Id.* at 1, 6. Petitioner's status report included references to parts of medical literature articles that were not filed in total for the record. *See id.*

In response to Petitioner's status report, Respondent filed a motion for a ruling on the record on August 30, 2021. Resp't's Mot., ECF No. 57. In her first motion for an extension of time to respond to Respondent's motion, Petitioner noted her initial belief "that no basis existed to respond." Pet'r's Mot., ECF No. 58. Nevertheless, she sought time "to resolve some matters with her expert." *Id.* She also noted that her June status report "list[ed] significant support for the concept that the flu vaccination, i.e.[,] H1N1, has been suspect in miscarriages for some time and the [sic] all flu vaccines have many of the same issues." *Id.* On October 14, 2021, Petitioner filed a second motion for an extension of time and explained that "[i]t turns out that the expert report filed in this matter by the prior attorney was not authorized to be submitted." Pet'r's Mot., ECF No. 59. She acknowledged that "[t]he question of reasonable cause prohibits [her counsel's] office from retaining experts as the chance of losing the investment is high." *Id.* at 2. However, Petitioner indicated a desire to continue with her claim and requested "two months to see if she can find expert help." *Id.* Petitioner filed her response to Respondent's motion for a ruling on the record on December 9, 2021. Pet'r's Resp., ECF No. 61. Petitioner also filed a motion for attorneys' fees on behalf of Mr. John McHugh on April 22, 2022. ECF No. 62. Respondent responded to Petitioner's motion for fees on April 26, 2022. ECF No. 63. Respondent did not file a reply to Petitioner's response to his motion for a ruling on the record. This matter is now ripe for consideration.

II. Evidence

a. Medical Records

Petitioner's medical history pre vaccination is significant for migraines and hypogammaglobulinemia.[4] Pet'r's Ex. 115 at 4, ECF No. 11-51; Pet'r's Ex. 102 at 14, ECF No. 11-38. Included in Petitioner's medical record is a letter from Petitioner's treating physician, Dr. Halfoun, during Petitioner's residence in Brazil from 2012 to 2015. Pet'r's Ex. 135, ECF No. 22-1. Dr. Halfoun noted to the best of her knowledge, Petitioner was in "good physical and mental health with no history of abortions, whether missed or induced." *Id.* On March 25, 2016, she was seen at the Stanford Health Care Emergency Department with complaints of abdominal pain and cramping, dysuria,[5] and hematuria.[6] Pet'r's Ex. 69 at 1–3, ECF No. 11-3. She was diagnosed with a potential UTI and a yeast infection. *Id.* Petitioner was seen again on May 15, 2016, for similar

[4] Hypogammaglobulinemia refers to "abnormally low levels of all classes of immunoglobulins in the blood[.]" *Dorland's* at 901.
[5] Dysuria is "1. painful urination. 2. any difficulty of urination." *Dorland's* at 585.
[6] Hematuria refers to "blood (erythrocytes) in the urine[.]" *Dorland's* at 834.

symptoms, including blood in the urine and stool, abdominal cramping, migraines, dizziness, and nausea. Pet'r's Ex. 71 at 1–2, ECF No. 11-5. She was diagnosed with a UTI and gastroenteritis.[7] *Id.*

On October 15, 2016, Petitioner was seen at the FCHC – Foothill Family Clinic for a tuberculosis ("TB") test and vaccinations for her immigration forms. Pet'r's Ex. 74 at 1, ECF No. 11-8. Petitioner denied that she was experiencing any changes to her menstrual cycle or that she could be pregnant. *Id.* Her medical records indicate that a urine pregnancy test administered during that visit was negative. Pet'r's Ex. 3 at 1, ECF No. 1-5; Pet'r's Ex. 74 at 2. Petitioner received a flu vaccine and an MMR vaccine that day. Pet'r's Ex. 75 at 2, ECF No. 11-9; Pet'r's Ex. 76 at 1, ECF No. 11-10.

On October 17, 2016, Petitioner returned to the Foothill Family Clinic for her TB test reading. Pet'r's Ex. 79 at 1–2, ECF No. 11-13. Her TB test revealed a positive purified protein derivative ("PPD"). Pet'r's Ex. 12 at 4 (also marked "#60"), ECF No. 10; Pet'r's Ex. 78 at 1, ECF No. 11-12. Petitioner was seen again at Foothill Family Clinic on October 21, 2016. Pet'r's Ex. 4 at 1, ECF No. 1-6. Her records indicate a positive pregnancy test with an estimated due date of June 6, 2017. *Id.* Her human chorionic gonadotropin ("HCG")[8] level of 267 was consistent with one to two weeks gestation, and she was referred to an OB/GYN. Pet'r's Ex. 84 at 2, ECF No. 11-18. Ten days later, on October 31, 2016, Petitioner's HCG level was 6,971, which is consistent with approximately three to four weeks gestation. Pet'r's Ex. 85 at 1, ECF No. 11-19. On November 6, 2016, Petitioner reported to the Santa Clara Medical Center Emergency Department with complaints of a small amount of vaginal bleeding lasting three days and one day of intermittent lower abdominal pain. Pet'r's Ex. 86 at 1, 26, ECF No. 11-20. The records from Santa Clara on this date note her gestation at seven weeks. *Id.* at 1.

The same day, Petitioner was referred for a gynecology consult for a "pregnancy of unknown location," and the recorded history noted that Petitioner had "pelvic cramping for a couple of weeks . . . [s]ince [the] bleeding started the pelvic cramping has changed in character and feels more like a 'heavy internal pain.'" *Id.* at 3. A physical exam revealed a small amount of old blood and a closed cervix with no active bleeding. *Id*. at 5. Petitioner's HCG level was 10,732, indicating approximately five to six weeks gestation. *Id.* at 5–6, 9. A pelvic ultrasound showed a "1.3 cm sac like structure without [a] yolk sac or fetal pole . . . there [wa]s surrounding decidual reaction[.]" *Id.* at 6. Based on the ultrasound, the attending physician noted that an "ectopic pregnancy cannot be excluded." *Id.* at 6, 15. The attending physician noted that the impression was likely a missed abortion, "given [Petitioner's] elevated BHCG beyond discriminatory zone, timeline, elevation of BHCG, and no identifiable [intrauterine pregnancy]." *Id.* at 6. The physician

[7] Gastroenteritis is "inflammation of the lining of the stomach and intestines, characterized by anorexia, nausea, diarrhea, abdominal pain, and weakness. Causes include food poisoning . . . ; viral infections . . . ; consumption of irritating food or drink; and sometimes psychological factors such as anger, stress, or fear." *Dorland's* at 764.

[8] Human chorionic gonadotropin ("HCG") or beta-human chorionic gonadotropin ("BHCG") is "a two-subunit glycopeptide hormone produced by syncytiotrophoblasts of the fetal placenta that maintains the function of the corpus luteum during the first few weeks of pregnancy, and is thought to promote steroidogenesis in the fetoplacental unit and to stimulate fetal testicular secretion of testosterone." *Dorland's* at 797.

continued, "[a]lthough [Petitioner had a] cystic structure within [the] endometrial canal [and] most likely [an] empty gestational sac, [we] cannot rule out early possible multiple gestation leading to [a] more elevated BHCG." *Id.* Petitioner was discharged on November 7, 2016, with final diagnoses including "[a]bdominal pain affecting pregnancy; [t]hreatened abortion; and [p]regnancy of unknown anatomic location." Pet'r's Ex. 5 at 1, ECF No. 1-7.

On November 15, 2016, Petitioner underwent another ultrasound, which revealed an "intrauterine cystic structure without [a] yolk sac or embryonic pole." *Id.* at 2; Pet'r's Ex. 89 at 1, ECF No. 11-23. The impression was a possible failed pregnancy. Pet'r's Ex. 87 at 2, ECF No. 11-21. She was asked to return in one week for a final ultrasound. *Id.* The physician also noted that Petitioner was reassured "[regarding] her prior MMR [vaccination]. There is no known actual risk of this in pregnancy, though it is not recommended to be given routinely as a matter of caution." *Id.*

The next day, Petitioner presented to Santa Clara Valley Obstetrics. Pet'r's Ex. 89 at 10. The physician noted that Petitioner likely had a "failed pregnancy although [a] pseudo sac (ectopic pregnancy) cannot be ruled out . . . correlated with [dilation and curettage ("D&C")] path to confirm [her] missed abortion." *Id.* at 1. The impression was a missed abortion at ten weeks based upon the date of her last period. *Id.* at 11. On November 23, 2016, Petitioner underwent a vacuum aspiration. Pet'r's Ex. 8 at 1, ECF No. 1-10. Petitioner's post-operative diagnosis was a "missed abortion (confirmed by [an] inspection of [the] gestational sac)." *Id.* The pathology of the uterine contents included "hemorrhagic fragments of tissue" with no clear gestational sac or fetal tissue. Pet'r's Ex. 91 at 2, ECF No. 11-25.

Petitioner returned to Foothill Family Clinic on December 7, 2016, for her second MMR vaccination. Pet'r's Ex. 93 at 1–2, ECF No. 11-27. A history of "miscarriage" was noted. *Id.* She was instructed to follow up for a third MMR vaccination in two weeks. *Id.*; Pet'r's Ex. 94 at 1, ECF No. 11-28. On December 26, 2016, Petitioner received her third MMR vaccination. Pet'r's Ex. 96 at 1, ECF No. 11-31. Her treater noted that a "pregnancy [sic] test [was] done earlier [that day and] was negative." Pet'r's Ex. 96-2 at 2, ECF No. 11-32. Petitioner's treater advised her against pregnancy within the next three months "as per [the MMR vaccine] manufacturer's recommendation." *Id.*

On April 3, 2017, Petitioner returned to Foothill Family Clinic OB/GYN with a complaint of pain and cramps for three weeks. Pet'r's Ex. 97 at 1–2, ECF No. 11-33. Petitioner's treater noted that Petitioner had heavy periods and cramps since her miscarriage. *Id.* On April 14, 2017, Petitioner underwent a pelvic ultrasound, which was normal. Pet'r's Ex. 12 at 7 (also marked "Ex. #63"), ECF No. 10; Pet'r's Ex. 98 at 1, ECF No. 11-34. Petitioner was seen again on November 21, 2017, for a requested pregnancy test. Pet'r's Ex. 101 at 1–2, ECF No. 11-37. The pregnancy test was positive, and her estimated date of delivery was July 18, 2018. *Id.* at 2.

Petitioner underwent testing and had a positive MMR titer on January 9, 2018, which showed she was immune to measles and rubella, but not to mumps. Pet'r's Ex. 104 at 1–2, ECF No. 11-40. A February 22, 2018 ultrasound showed normal fetal anatomy and development with normal movement. Pet'r's Ex. 108 at 2, ECF No. 11-44. On May 3, 2018, Petitioner returned for another ultrasound, which revealed normal growth of the fetus and normal amniotic fluid. Pet'r's

Ex. 113 at 2, ECF No. 11-49. On June 13, 2018, Petitioner presented to Foothill Clinic OB/GYN. Pet'r's Ex. 115 at 6, ECF No. 11-51. She underwent testing that showed trace protein in her urine and a slightly elevated blood pressure ("BP") of 121/80.[9] *Id.* A check-up on June 20, 2018, revealed that Petitioner's protein level in her urine had returned to normal and her BP was 109/73.[10] *Id.* On June 27, 2018, Petitioner had an elevated BP of 154/92 and increased protein in her urine. *Id.* at 6–7. She was referred to Labor and Delivery to rule out preeclampsia. *Id.* On June 28, 2018, Petitioner was admitted to Santa Clara Valley Medical Center for induction of labor. Pet'r's Ex. 119 at 3, 28, ECF No. 11-55; Pet'r's Ex. 8 at 2–3. Her preeclampsia was noted to be severe, and her liver enzymes were greater than twice the normal level. Pet'r's Ex. 8 at 4. Petitioner received two doses of misoprostrol[11] to induce labor. *Id.* However, her preeclampsia labs worsened, and her treaters determined a cesarean section was necessary. *Id.* Later the same day, Petitioner gave birth to a healthy baby boy with Apgar scores[12] of seven and nine, at one and five minutes, respectively. *Id.*

b. Affidavits

i. Petitioner's First Affidavit

Petitioner filed an affidavit entitled "Testimony about Nature, Extent and Residual Effects." Pet'r's Ex. 131, ECF No. 11-67. She explained that her "testimony intends to complement the analysis of the damage caused by the [v]accine [i]njury claimed" in her petition. *Id.* at 1. Petitioner then described the negative impact that her spontaneous abortion had on her life, health, and opinion of the United States healthcare system. *Id.* She reiterated that she was ill-informed at the time of her vaccination and that she did what her treaters recommended, without understanding the potential risks. *Id.* at 1–2.

ii. Petitioner's Second Affidavit

Petitioner filed a second affidavit entitled "Corrections according to Guidelines for Practice And fulfilling Initial Order . . . ." Pet'r's Ex. 133, ECF No. 11-68. This document explained her numbering system for the filing of her exhibits. *See id.* Petitioner cited to several exhibit numbers in support of her claim that do not appear to have been filed in the record. *See id.*

iii. Petitioner's Status Report

Petitioner's status report filed on February 3, 2020, responded to Respondent's Rule 4(c) report. Pet'r's Ex. 141, ECF No. 31. Although filed as a status report, I will construe this filing as

[9] Based on this result, Petitioner's treater made a note to "check [Petitioner's] BP carefully [at the] next [visit]." Pet'r's Ex. 115 at 6.

[10] Petitioner's treater made the same notation to check Petitioner's BP "carefully" at her next visit. Pet'r's Ex. 115 at 6.

[11] Misoprostol is "used orally in combination with mifepristone to terminate pregnancy, acting to soften and ripen the cervix and induce uterine contractions." *Dorland's* at 1169.

[12] The Apgar score or scale is "a numerical expression of the condition of a newborn infant, usually determined at 60 seconds after birth, being the sum of points gained on assessment of the heart rate, respiratory effort, muscle tone, reflex irritability, and color." *Dorland's* at 1682.

an affidavit because of the nature of its contents, including Petitioner's own opinions and beliefs. *See generally id.*

Petitioner's status report concluded with the following:

> The Petitioner has provided great service sembling [sic] evidence to support the US [sic] vaccination system to understand more about how vaccines can harm pregnant women and cause the death of an in utero children [sic]. This claim is extremely relevant to the future of human lives. Because these vaccines are still today recommended without proper care, risking to cause [sic] more deaths.

Id. at 20.

c. Petitioner's Expert Report

Petitioner filed an expert report written by Dr. Leslie Hansen Lindner, an obstetrician and gynecologist with Charlotte Obstetric & Gynecologic Associates. Pet'r's Ex. A. Dr. Hansen Lindner included a timeline of Petitioner's medical history beginning with her vaccination and initial (negative) pregnancy test on the same date. *Id.* at 1. She noted the Center for Disease Control's ("CDC") recommendation "that the MMR vaccine not be administered to a pregnant woman due to the risk of a live attenuated vaccine crossing the placenta and causing an infectious risk to the developing fetus." *Id.* Dr. Hansen Lindner then highlighted that Petitioner received her "MMR vaccine at the time she was pregnant, or immediately prior thereto." *Id.* Petitioner then maintained "appropriate hormonal levels" for at least two weeks post vaccination. *Id.* She noted that "[t]here is no obvious cause for the miscarriage." *Id.* Dr. Hansen Lindner also noted that Petitioner "did not show any immunity to [m]umps" post-vaccination. *Id.*

Petitioner included in her June 21, 2021 status report an excerpt from an unfiled study[13] of a possible association between a vaccine containing pH1N1 and spontaneous abortion. ECF No. 56 at 2–3. The article was not filed in total, and the excerpt noted an association "only among women vaccinated in the previous influenza season with [a] pH1N1-containing vaccine." *Id.* Petitioner asserted that she "believes she received the flu vaccine in 2013 and may have had the flu in 2012, but due to the pandemic in Brazil, she has no access to those medical records." *Id.* at 4–5. Petitioner included in her excerpt the authors' statement that the study "does not and cannot establish a causal relationship between repeated influenza vaccination[s] and [spontaneous abortion.]" *Id.* She noted that "the flu vaccine has a high rate of adverse reactions, mostly mild." *Id.* at 5. Petitioner concluded this status report by noting that despite finding Dr. Hansen Linder's report to be inadequate, she has "not been able to find new expert support for this case," and "will need to proceed as is." *Id.* at 6.

d. Additional Filed Evidence[14]

[13] Abstract of J.G. Donahue, et al., *Association of spontaneous abortion with receipt of inactivated influenza vaccine containing H1N1pdm09 in 2010–11 and 2011–12,* 35(40) VACCINE 5314–22 (2017).

[14] Petitioner filed medical and scientific literature in this case, but not every filed item factors into the outcome of this Decision. While I have reviewed all the medical literature submitted in this case, I refer only to those articles that are most relevant to my determination and/or are central to Petitioner's case—

Petitioner filed an article entitled *Vaccinations in Pregnancy* that lists common symptoms that result from measles, mumps, and rubella. Pet'r's Ex. 146, ECF No. 32-5.[15] A measles infection presents with "fever, coryza,[16] a generally ill appearance, and a confluent, erythematous, maculopapular rash," and in very rare cases, death, "often secondary to pneumonia or encephalitis." *Id.* at 4. Mumps "can lead to parotitis,[17] meningoencephalitis,[18] and orchitis."[19] *Id.* Rubella is "usually a benign infection in adults," but it can result in birth defects. *Id.* Although the study in this article "showed no evidence that [the] rubella vaccine caused any fetal abnormalities or congenital rubella syndrome[,]" the vaccination of pregnant women is not recommended due to "theoretic risk." *Id.*

A filing by Petitioner that focuses on mumps during pregnancy notes that "infection during the first trimester of pregnancy has been associated with an increased rate of spontaneous abortion." Pet'r's Ex. 147 at 1, ECF No. 32-6.[20] It notes that the "vaccine virus has been been [sic] recovered from the placenta, but not from the fetal tissues of pregnant women who were vaccinated before undergoing elective abortions." *Id.* Petitioner filed an abstract that also notes the presence of the mumps virus in the placenta following vaccination, but the entire article was not filed. Pet'r's Ex. 148, ECF No. 32-7.[21]

In her exhibit list, Petitioner identified several pieces of evidence that she related back to specific exhibits. ECF No. 32. For example, Petitioner listed under "Evidence 10 at Exhibits #1 to #5, #7 to #8, #11 to #12, #17 to #53" an article designated #28 and described as "Medical Article about Rubella vaccination in Pregnancy." *Id.* at 2–3. I am unable to locate such an article in the filed record. As previously mentioned, many of Petitioner's listed exhibits do not appear to be filed and therefore are not available for consideration.

III. Summary of the Parties' Arguments

a. Respondent's Motion for Ruling on the Record

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just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

[15] D.K. Sur, et al., *Vaccinations in Pregnancy,* 68(2) AM. FAMILY PHYS. 299–309 (2003).

[16] Coryza is acute rhinitis. Acute rhinitis is "an acute congestion of the mucous membrane of the nose, marked by dryness, followed by increased mucous secretion from the membrane, impeded respiration through the nose, and pain." *Dorland's* at 1639.

[17] Parotitis is "inflammation of the parotid gland." *Dorland's* at 1384.

[18] Meningoencephalitis is "inflammation of the brain and meninges." *Dorland's* at 1134.

[19] Orchitis is "inflammation of a testis, marked by pain, swelling, and a feeling of weight, often seen accompanying epididymitis . . . . It may occur idiopathically or be associated with conditions such as mumps, gonorrhea, filarial disease, syphilis, or tuberculosis." *Dorland's* at 1333.

[20] *Infections During Pregnancy – Mumps Virus,* MUMPS IN PREGNANCY, perinatology.com.

[21] Abstract of T. Yamauchi, et al., *Transmission of Live, Attenuated Mumps Virus to the Human Placenta,* 290 N. ENGL. J. MED. 710–12 (1974).

Respondent filed his motion for a ruling on the record dismissing Petitioner's claim on August 30, 2021. Resp't's Mot. Respondent argued that "Petitioner's expert, Dr. Hansen-Lindner, has failed to offer a scientifically reliable theory causally connecting the MMR or flu vaccine to miscarriage in general, nor has [P]etitioner demonstrated a logical sequence of cause and effect or a medically acceptable temporal relationship" between her vaccinations and alleged injuries. *Id.* at 11. Respondent noted that Petitioner did not file a curriculum vitae for her expert, and the report did not list her educational or professional background. *Id.* at 12. Atrium Health's website lists her board certifications in obstetrics and gynecology and states she has been an employee since 1996. *Id.* at 12–13 (citing https://atriumhealth.org/provider-profile/leslie-hansen-lindner-1649205204). Respondent also noted that she completed her residencies in obstetrics and gynecology at the University of Pennsylvania School of Medicine. *Id.* at 13.

Respondent asserted that Dr. Hansen Lindner did "not include any opinion with respect to vaccine causation." *Id.* Respondent further argued that the limited medical literature that Petitioner filed "sets forth no theory of how the discussed flu vaccines would cause spontaneous abortion (miscarriage) and includes a conclusion which states 'this study does not and cannot establish a causal relationship between repeated influenza vaccination and spontaneous abortion.'" *Id.* at 13–14. The article that Petitioner submitted discusses how the flu vaccine can increase the risk of chorioamnionitis[22] and lead to miscarriage, but Respondent argued that there is no evidence in this case that Petitioner developed chorioamnionitis. *Id.* at 14.

Respondent asserted that "[P]etitioner's treating providers did not ascribe causation to either of the vaccinations." *Id.* at 15. In fact, Dr. Graham noted that "there is no known actual risk of [vaccination] in pregnancy, though it is not recommended to be given routinely as a matter of caution." *Id.* (citing Pet'r's Ex. 87 at 2). Lastly, Respondent argued that without a sound theory and a logical sequence of cause of effect, "[P]etitioner has failed to establish the requisite appropriate temporal relationship between the MMR and/or flu vaccine and her miscarriage and other alleged injuries." *Id.* at 17.

b. Petitioner's Response

Petitioner filed her response on December 9, 2021. Pet'r's Resp. Petitioner argued that "[t]he rubella part of the [MMR] vaccine is a live virus vaccine. Rubella causes miscarriage." *Id.* at 1. She relied on the CDC's warning that "congenital rubella syndrome is a condition that occurs in a developing baby in the womb whose mother is infected with the rubella virus," and can result in serious birth defects or miscarriage. *Id.* She continued that "[i]t is well understood that, if the disease can do it, the vaccine can more likely than not do it, too." *Id.* at 2.

Petitioner asserted that "[l]iterature provides all the information required" to establish her burden under *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Id.* at 1.

[22] Chorioamnionitis is "inflammation of the chorion and amnion." *Dorland's* at 354. The chorion is "in human embryology, the cellular, outermost extraembryonic membrane, composed of trophoblast lined with mesoderm; it develops chorionic villi about 2 weeks after fertilization, is vascularized by allantoic vessels a week later, and gives rise to the fetal part of the placenta." *Id.* at 355. The amnion is "the thin but tough extraembryonic membrane of reptiles, birds, and mammals that lines the chorion and contains the embryo and later the fetus, with the amniotic fluid around it[.]" *Id.* at 64.

Pursuant to *Althen*, Petitioner stated that "all that must be proven is that the injury is possible, not probable, and that a known mechanism is in place, i.e., the known characteristics of rubella and that the timing is likely." *Id.* at 3. Relying on a 21-day onset period for adverse reactions to live, attenuated vaccines, Petitioner argued that her miscarriage at three weeks post vaccination is within an appropriate timeframe for vaccine causation. *Id.* Petitioner concluded that "the live-attenuated rubella virus in the vaccine caused the replication of the wild virus in [Petitioner] that, in turn more likely than not, caused the miscarriage." *Id.*

IV. Applicable Law

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where, in the exercise of their discretion, they conclude that doing so will properly and fairly resolve the case. *See* 42 U.S.C. § 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of a hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided cases on the papers in lieu of hearing and those decisions were upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that the special master acted within his discretion in denying an evidentiary hearing); *Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

To receive compensation under the Vaccine Act, a petitioner must demonstrate either that: (1) the petitioner suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table set forth at 42 U.S.C. § 300aa-14, as amended by 42 C.F.R. § 100.3; or (2) that petitioner suffered an "off-Table injury," one not listed on the Table, as a result of his receiving a covered vaccine. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006). Petitioner does not allege a Table injury in this case; thus, she must prove that her injury was caused-in-fact by a Table vaccine.

In the seminal case of *Althen v. Sec'y of the Dept. of Health & Hum. Servs.*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d at 1278–79. The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355–56 (Fed. Cir. 2006) (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound

and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen,* 35 F.3d at 549.

Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). This may be accomplished in a number of ways. "Reliability and plausibility of . . . pathogenesis can be bolstered by providing evidence that at least a sufficient minority in the medical community has accepted the theory, so as to render it credible." *See Pafford v. Sec'y of Health & Hum. Servs.,* No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004). Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu*, 569 F.3d at 1380.

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77. The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *de Bazan,* 539 F.3d at 1352; *Shapiro v. Sec'y of Health & Hum. Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014). The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

A petitioner who satisfies all three prongs of the *Althen* test has established a prima facie showing of causation. *Hammitt v. Sec'y of Health & Hum. Servs*., 98 Fed. Cl. 719, 726 (2011). When and if a petitioner establishes a prima facie case, the burden then shifts to the government to prove that an alternative cause, unrelated to the administration of the vaccine, was the "sole substantial factor" in causing the alleged injury. *de Bazan*, 539 F.3d at 1354; *see also Hammitt*, 98 Fed. Cl. at 726 (explaining that the respondent's burden is to show that the "factor unrelated" was the "sole substantial factor" in causing the injury). Additionally, a factor unrelated "may not include 'any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness or condition.'" 42 U.S.C. § 300aa-13(a)(2).

V. Analysis

In Petitioner's response to Respondent's motion for a ruling on the record, Petitioner asserts that "all that must be proven is that the injury is possible, not probable, and that a known mechanism is in place." Pet'r's Resp. at 2. This is not the standard. Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. § 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1324. Furthermore, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Id.* at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford*, 451 F.3d at 1355. To be clear, proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.,* 931 F.2d 867, 873 (Fed. Cir. 1991). However, a petitioner may not receive a Vaccine Program award based solely on her assertions. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 13(a)(1).

In the present case, Petitioner's expert, Dr. Hansen Lindner, did not identify a biological mechanism for the cause of Petitioner's spontaneous abortion. Instead, her letter included the CDC's recommendation against MMR vaccination for pregnant women. She did not offer an opinion on whether Petitioner's vaccinations had any effect on Petitioner's pregnancy. Dr. Hansen Lindner's letter did not otherwise offer any opinion on the cause of Petitioner's spontaneous abortion. Indeed, she stated in her letter that there was no obvious cause. Pet'r's Ex. A at 1. Without a clear medical theory casually connecting the vaccination and injury from Petitioner's expert, I will turn to the medical literature Petitioner filed.

The articles and online excerpts that Petitioner filed provide additional context and explain the basis for the CDC's recommendation against receipt of the MMR vaccine during pregnancy. The *Vaccination in Pregnancy* article states that rubella can result in birth defects if the virus is transmitted from the mother to the fetus during pregnancy. Pet'r's Ex. 146. While this risk has been documented with respect to the wild virus, the authors found "no evidence that [the] rubella vaccine caused any fetal abnormalities or congenital rubella syndrome." *Id.* at 4. The article explains that with respect to the vaccine, the authors' only aim is to note evidence of a "theoretic risk." *Id.* Indeed, there is no evidence in this case that Petitioner developed a rubella infection. Petitioner did not report any symptoms of rubella at any point during her pregnancy. Her medical providers never suspected that she suffered from rubella or any other infection during her pregnancy. Furthermore, there is no evidence that, during her pregnancy, the rubella virus was transmitted through the placenta and subsequently infected the fetus. There was concern, however, that Petitioner's pregnancy may have been ectopic or otherwise nonviable (e.g., with an ultrasound that revealed an intrauterine cystic structure without a yolk sac or embryonic pole), completely unrelated to her receipt of the vaccines. Petitioner has not produced preponderant evidence that her spontaneous abortion was due to a rubella infection from the MMR vaccine.

A second article filed by Petitioner discussed the potential risk of spontaneous abortion in the first trimester as a result of the mumps infection. Pet'r's Ex. 147. This article also cited a study that did not find evidence of the mumps virus in fetal tissue from women vaccinated during

pregnancy. *Id.* Dr. Hansen Lindner highlighted the notation in Petitioner's medical records that she did not show any immunity to mumps. Pet'r's Ex. A at 1. This is evidence that Petitioner did not develop a mumps infection and therefore did not transmit any such infection to the fetus during pregnancy.

Petitioner's assertion that the flu vaccine has an association with miscarriages is unsupported. In her status report immediately preceding Respondent's motion for a ruling on the record, Petitioner included an excerpt from an unfiled study of a possible association between a vaccine containing pH1N1 and spontaneous abortion. ECF No. 56 at 3. The article was not filed in total, and the excerpt noted an association "only among women vaccinated in the previous influenza season with [a] pH1N1-containing vaccine." *Id.* The authors were clear that the study does not and cannot establish a causal relationship between "repeated influenza vaccinations and [spontaneous abortion.]" *Id.* As Petitioner notes, the flu vaccine is recommended for pregnant women. She also asserts that a section of the CDC website entitled *Vaccines for Your Children: Vaccine for Flu* "tends to show that a flu vaccine can cause this injury." *Id.* at 5. This webpage focuses on the vaccination of young children and includes a frequently-asked-question section that asks, for example, *"why should my child get a flu vaccine"* and *"is the flu serious?" See* https://www.cdc.gov/vaccines/parents/diseases/flu.html. Incidentally in response to the question, *"should pregnant women get vaccinated?,"* the CDC website states "yes" and notes a woman "can be vaccinated during any trimester of [her] pregnancy." *Id.* The webpage does not discuss any potential risk of miscarriage posed by the flu vaccine.

Petitioner did not file persuasive evidence to support a claim that her October 15, 2016 influenza vaccination could be the cause-in-fact of her spontaneous abortion. Dr. Hansen Lindner made no mention of the flu vaccine in her letter. Petitioner's medical records do not include her vaccination history. Petitioner presented no evidence that she received a vaccine containing pH1N1 in the year preceding her spontaneous abortion, or any prior year. She asserted that she "believes she received the flu vaccine in 2013 and may have had the flu in 2012." ECF No. 56 at 4. Even assuming that is true, Petitioner's medical history is still inconsistent with the case studies briefly described in her excerpted medical literature.

Petitioner has not provided preponderant evidence that her MMR or flu vaccines can cause spontaneous abortion, or that they did in her case. Petitioner argues that a three-week period between vaccination and spontaneous abortion is appropriate to infer causation. Without any biological mechanism for context, it is impossible to determine an appropriate temporal relationship in this case. In any event, a temporal relationship would be of no consequence without a medical theory and a logical sequence of cause and effect.

Of note, in multiple filings, Petitioner has expressed dissatisfaction with her expert report. ECF Nos. 56, 59. She also acknowledged reasonable basis concerns that she did not subsequently address in full. ECF No. 59. Indeed, she has been unable to obtain an additional expert report in support of her claim, despite multiple opportunities to do so. While this Program does contemplate *pro se* petitioners, all claimants, regardless of representation status, must provide preponderant evidence of vaccine causation. It is clear from the medical records that there is not preponderant evidence that Petitioner's vaccines caused her spontaneous abortion. In fact, Petitioner's claim is also contrary to her partially submitted literature. To overcome the purported lack of reasonable

basis in this case, Petitioner relies on a general recommendation from the CDC, and further argues that "the [V]accine [A]ct forbids use of any idiopathic theory as to an unrelated cause to defeat a [] claim." Pet'r's Mot. Fees at 2, ECF No. 62. Petitioner is correct that once a prima facie case is established, Respondent cannot simply assert the possibility of an idiopathic cause to successfully rebut a claim. In this case, however, Petitioner has not established a prima facie case. Furthermore, this is not a Table claim. As such, there is no presumption of causation based solely off an identified vaccine and a specific injury. Respondent therefore has no burden to provide any evidence or rebut any of Petitioner's evidence.

VI. Conclusion

Petitioner has experienced an immeasurable loss, and I have reviewed the entire record in an effort to understand what happened to her. In this Program, many of the most serious and life-changing conditions that petitioners experience remain idiopathic. As noted in the case filings, first trimester spontaneous abortions are not rare events. Despite their frequency, it can be difficult to determine the cause in many cases. This, unfortunately, is such a case. Petitioner has not met her burden to establish that but-for her vaccinations, she would not have suffered a spontaneous abortion and severe preeclampsia. Therefore, her claim must be **DISMISSED**.

IT IS SO ORDERED.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master