In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 05-81V
January 31, 2007
To be Published

APRIL SPATES,	*	
	*	
Petitioner,	*	
	*	
v.	*	Entitlement; MMR alleged
	*	to have caused miscarriage
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	but prior MMR made
	*	petitioner immune to rubella
	*	virus component of vaccine
Respondent.	*	

Thomas P. Gallagher, Somers Point, NJ, for petitioner.
Alexis B. Babcock, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

Petitioner filed a petition dated January 10, 2005, under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that she and her fetus suffered injuries after receipt of MMR vaccine on January 7, 1994. Petition, at ¶¶ 2, 5, 6, and 7. Petitioner had a

[1] Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

"missed abortion" (miscarriage) and alleges that she sustained emotional and physical injuries due to the death of her fetus and excessive continued vaginal bleeding, depression, and embarrassment. Id. at ¶ 7.

On January 6, 2006, the undersigned issued an Order to Show Cause why the allegations on behalf of the unborn child should not be dismissed because petitioner did not have representative capacity to sue for death damages on behalf of her fetus under New York State law. 2006 WL 197316 (Fed. Cl. Spec. Mstr. Jan. 6, 2006). Petitioner filed a status report on February 6, 2006 voluntarily dismissing that aspect of her claim.

A hearing on the issue of whether MMR caused her miscarriage was held on November 20, 2006. Testifying for petitioner was Dr. Frank Sindoni, an obstetrician-gynecologist. Testifying for respondent was Dr. Robert L. Brent, a teratologist (expert in the study of birth defects).

FACTS

Petitioner was born on November 22, 1967. Ex. B, p. 57.

On January 7, 1994, she received MMR vaccine.

On January 28, 1994, three weeks later, she went to Brookdale Clinic, complaining of feeling nauseated. She had thrown up in the morning. Med. recs. attached to petition at p. 99.

On February 1, 1994, she went to Brookdale Hospital Medical Center. The CRL (crown rump length) of the embryo was 0.54 cm, but there were no cardiac activities. *Id.* at 103. The intrauterine growth was 8-10 weeks by size. *Id.* at 98.

On February 4, 1994, Brookdale Clinic noted no fetal heart rate was detected. Petitioner desired termination. There was no bleeding and no abdominal pain. *Id.* at 99.

On February 8, 1994, Dr. Murray and Dr. H. Coke of Brooklyn Hospital Medical Center did a D & C (dilatation and curettage) for a missed abortion without complications. *Id.* at 7. Petitioner had no prior medical history. *Id.* at 8. She had a womb scrape and was alert and oriented. *Id.* at 10. She had no signs or symptoms of vaginal bleeding. *Id.* at 12.

On May 5, 1997, petitioner went to Brookdale University Hospital and Medical Center, complaining of vaginal bleeding from April 27, 1997 for two days. *Id.* at 71.

Other Submitted Materal

Petitioner filed the report of Dr. Harold E. Buttram. P's Fifth Submission. He states petitioner had two prior miscarriages before her 1994 miscarriage. *Id.* at 1. He thinks that petitioner's elevated amylase of 94 on January 28, 1994 was due to acute pancreatitis caused by the mumps portion of the MMR vaccine. *Id.* at 3. (Petitioner was never diagnosed with pancreatitis.) His opinion was that MMR caused petitioner's miscarriage. *Id.* at 4.

From pages 4-6 of his report, Dr. Buttram discusses how MMR causes autism. (Petitioner was never diagnosed with autism.) He concludes that MMR caused petitioner measles encephalitis and/or mumps meningitis and a measles-related enteritis, as well as a prolonged smoldering measles encephalitis. *Id.* at 6. (Petitioner has never been diagnosed with measles encephalitis, mumps meningitis, measles-related enteritis, or prolonged smoldering measles encephalitis.)

Attached to Dr. Buttram's report is an article he wrote entitled "Vaccine Safety Testings: What are they? Why are they needed? Whay [sic] are they <u>not</u> being done? (Concerning the Current Epidemics of Childhood Autism, Learning Disabilities, and Medical-Legal Issues Surrounding the Shaken Baby Syndrome)." *Id.* at 9 (emphasis included in title of article). (There

are no issues in this case dealing with childhood autism, learning disabilities, or shaken baby syndrome.)

Following Dr. Buttram's article is a letter from Dr. F. Edward Yazbak concerning autism research and an article entitled "Withdraw the Report," referring to the Institute of Medicine's report on vaccines and autism. *Id.* at 15-20. This is followed by an article by Goldman and Yazbak entitled, "An Investigation of Association between MMR Vaccination and Autism in Denmark," with the journal in which it was published unspecified. *Id.* at 21-25. Charts on autism follow until page 29. This is followed by another article on autism in children connected to measles virus genomic RNA in cerebrospinal fluid. *Id.* at 31-38.

The undersigned finds Dr. Buttram's report mostly irrelevant because the conclusion Dr. Buttram reaches that MMR vaccine caused petitioner's miscarriage is based on his own diagnoses that doctors never made in this case and on Dr. Buttram's discussion of autism which is not an issue in this case. The undersigned strikes all the articles submitted after Dr. Buttram's report as irrelevant. Dr. Buttram's C.V., filed as petitioner's Third Submission, shows that Dr. Buttram practices as a family physician, not as an obstetrician-gynecologist or a teratologist.

Respondent filed Ex. A, Tab 1, the MMWR (Morbidity and Mortality Weekly Report), Vol. 38, No. 17, pp. 289-93 (May 5, 1989), entitled "Current Trends. Rubella Vaccination during Pregnancy - United States, 1971-1988." In Table 1 (Pregnancy outcomes for 683 recipients of RA 27/3 vaccine), among the 32 women who were immune because they had previously received rubella vaccine, there were 30 live births, one spontaneous abortion and still birth, and one whose outcome was unknown. *Id.* at 290.

The CDC (Centers for Disease Control) established a VIP (Vaccine in Pregnancy) registry in 1971 for women who received either of two prior rubella vaccines within three months before or after conception. None of the 290 infants born to the 538 women entered into the VIP registry through April 1979 had defects indicative of congenital rubella syndrome (CRS). *Id.* at 289. In 1979, a new strain was introduced (RA 27/3) and concern arose that this new attenuated-virus vaccine might have greater fetotropic and teratogenic potential than the earlier vaccines because it had been isolated from and propagated in human tissue. *Id.* From 1979 through December 31, 1988, the VIP registry received reports from 272 enrollees. Outcomes of the pregnancies were known for 254 women. Thirteen (5%) had spontaneous abortions. *Id.* Five of these women were vaccinated during the period of highest risk. *Id.* at 290. Findings were compatible with the 92 women who were vaccinated within one week before to four weeks after conception. Five (6%) had spontaneous abortions. *Id.* The authors concluded that their data since 1979 did not show evidence that the RA 27/3 rubella vaccine administered in pregnancy can cause defects indicative of CRS. *Id.* at 291. This was consistent with the results from the prior two strains of rubella vaccine. "Therefore, the observed risk for CRS following rubella vaccination continues to be zero." *Id.* These results were also consistent with the results in Germany and the United Kingdom where rubella vaccine was not associated with CRS among infants whose mothers were vaccinated around the time of conception. *Id.* The risks are comparable with the 2-3% rate of major birth defects observed in the absence of exposure to rubella vaccine. *Id.* at 292.

The authors note that rubella vaccine viruses can cross the placenta and infect the fetus. *Id.* This occurred in 3% of children whose mothers received RA 27/3 vaccine and 20% of children who received the prior two strains of rubella vaccine. Thus, their advice continued to be

not to vaccine pregnant women. But if a pregnant woman did receive the rubella vaccine, since the risk of CRS was so small as to be negligible, she should not be advised to abort. *Id.* Routine laboratory screening for both pregnancy and rubella antibody was not necessary before administration of the rubella vaccine. *Id.*

TESTIMONY

Dr. Frank Sindoni testified for petitioner. Tr. at 3. He graduated from the University of Medicine and Dentistry of New Jersey in 1978, and has been in private practice as an obstetrician-gynecologist since 1982. Tr. at 4, 5. His opinion is that MMR vaccine caused petitioner's miscarriage. Tr. at 6. He said there was a logical sequence of cause and effect in that petitioner's embryo was in gestation during the time when the vaccine would have had an impact on it. *Id.* Petitioner had an ultrasound when she was five weeks pregnant on February 7, 1994. She received the MMR vaccination on January 7, 1994 when she was two weeks into her pregnancy. *Id.* The plausible medical theory is that the Centers for Disease Control (CDC) issued a report that German measles (rubella) vaccine can cause a miscarriage in a small percentage of cases.[2]

Dr. Sindoni knows the gestational age of the embryo because of the ultrasound. Tr. at 7. The embryo had a CRL (crown rump length) of 0.54 cm, meaning a five-week pregnancy. Tr. at 8. The February 1, 1994 record states she had an 8-10 week pregnancy by size, but this was inaccurate. The ultrasound was more accurate as to the size of the embryo. Tr. at 9.

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[2] HHS, not the CDC, is responsible for the MMWR which is respondent's Ex. A, Tab 1. The report does not say rubella virus in the MMR vaccine causes miscarriage. Out of 32 previously immunized women who received MMR vaccine while pregnant, one pregnancy ended in a spontaneous abortion (miscarriage). See page 290. The authors are silent about the cause.

Dr. Sindoni testified that the most likely cause of petitioner's nausea and vomiting was the pregnancy. Tr. at 10. Dr. Sindoni limited his opinion on the cause of petitioner's miscarriage to the rubella or German measles part of the MMR. Tr. at 11.

He stated that MMR causes miscarriage in two to three percent of vaccinees, based on the CDC report.[3] In the study, they cultured rubella virus out of fetal tissue. But, here, Brookdale Hospital did not preserve petitioner's placental tissue or fetus for culturing. Without a tissue analysis, one cannot say that chromosomal problems caused petitioner's miscarriage. Tr. at 13.

Dr. Sindoni said that there is confusion over the fetus' vulnerable period. It is called the "all or none period" and runs from four to five weeks after the last menstrual period. Tr. at 15. The point of ovulation starts from the last menstrual period. Dr. Sindoni stated that respondent's expert Dr. Brent's timing of gestation is inaccurate because Dr. Brent relies upon the estimate that the size of the uterus showed a fetus of from 8-10 weeks. *Id.* But Dr. Sindoni said that that examination was incorrect. He relies on the ultrasound estimate most of the time. *Id.* In the all or none period, the embryo is so small that the effect of the rubella virus on the developing cells completely destroys them so there is no further embryonic growth, resulting in fetal death and miscarriage. Tr. at 16. The immune status on petitioner's chart showed she was immune to rubella. Dr. Sindoni agreed that her prior immunity to rubella decreased the likelihood that the rubella virus reached her fetus. *Id.* But even in immune patients, the virus can reinfect them. Tr.

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[3] Again, HHS, not the CDC, generated the MMWR which is R's Ex. A, Tab 1. The report actually states that two to three percent of women give birth to babies with major defects in the absence of exposure to rubella vaccine. See page 292. The authors were not referring to vaccinees. Among vaccinees, and the authors do not distinguish among those previously immunized with MMR, the major birth defect rate is comparable to the baseline, i.e., 1.7 percent for the RA 27/3 vaccine and 1.2 percent for the three strains since 1971. *Id.*

at 17. However, he found it hard to quantify the decrease in the likelihood of petitioner's embryo having an adverse reaction to rubella vaccine because he did not know what strand[4] of rubella virus was in the MMR vaccine petitioner had received before and what strand was in the MMR vaccine she received on January 7, 1994. In the MMWR (Morbidity and Mortality Weekly Report), Table 1, in someone with pre-vaccine immunity who received MMR vaccine while pregnant, there was one spontaneous abortion. Tr. at 18.

Petitioner's last menstrual period before her vaccination was November 1993. Tr. at 20. Most miscarriages are due to chromosomal problems. There is a 15 % rate of miscarriage generally. Tr. at 22. Out of 22 women,[5] there should be three miscarriages[6] if there is a 15% miscarriage rate, but in the MMWR Table 1, there was only one. *Id.* Therefore the abortion rate was lower than average among vaccinees who had immunity from a prior MMR. *Id.*

Petitioner's smoking and drinking were risk factors for a miscarriage. *Id.* On February 1, 1994, petitioner admitted to smoking three-quarters of a pack a day. Tr. at 23. She had past miscarriages which increased the risk for her to miscarry again. Tr. at 25. She had two spontaneous abortions (miscarriages) at three and one-half and four months of gestation. *Id.*

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[4] All during his testimony, Dr. Sindoni referred to the "strand" of rubella virus in the MMR vaccine until Dr. Brent, during his own testimony, corrected him by stating that the correct word was "strain," a correction with which Dr. Sindoni wholeheartedly agreed. Tr. at 59.

[5] Table 1 on page 290 of R. Ex. A, Tab 1, lists 32, not 22, previously-immune women.

[6] Since there were 32, not 22, women who were immune to rubella from prior MMR vaccination, using the 15% miscarriage rate, there should have been 5 miscarriages, not 3, if the normal rate had occurred among the women in Table 1 of R. Ex. A, Tab 1. Instead, there was one miscarriage among immune vaccinees.

Dr. Sindoni found it tough to pick the cause of petitioner's miscarriage from the four risk factors. Tr. at 26-27. Since the administration of MMR vaccine is contraindicated in pregnancy, he would put MMR above smoking, drinking, and her two prior miscarriages as the cause. Tr. at 27. Petitioner had three deliveries without complication. *Id.*

Dr. Robert L. Brent testified for respondent. Tr. at 29. Besides being a medical doctor, he has a Ph.D in embryology and biophysics, and specializes in reproductive problems. He is head of a research institute called the Stein Research Center that deals with problems of reproduction and congenital malformations. Tr. at 30. He was one of the founders of the Teratology Society, devoted to birth defects, and was elected its president. He was the editor of the *Birth Defects Journal* for 17 years. Tr. at 30. Dr. Brent has been involved in reproductive problems for 55 years. Tr. at 31. He publishes extensively in the area, having co-authored eight books and monographs, and written 410 articles and 319 abstracts. He is a reviewer for *Reproductive Toxicology*, *The New England Journal of Medicine*, *Pediatric Research*, *Birth Defects Journal*, and *Obstetrics and Gynecology*. *Id.* He was invited to the Pasteur Institute to discuss the risks and benefits of immunizing pregnant women. *Id.* The Teratology Society has created a lectureship in his name.

Dr. Brent testified that MMR is not contraindicated for pregnant women, but litigation reduces the administration of the vaccine to them. Tr. at 32. In his opinion, MMR vaccine did not cause petitioner's miscarriage because petitioner was immune to the effects of MMR due to her prior MMR. Tr. at 33. In tables of spontaneous abortion, the National Institute of Environmental Sciences states in *The New England Journal of Medicine* that 20-25 % of

embryos die because of chromosomal abnormality. Tr. at 34. Petitioner's smoking, drinking, and history of spontaneous abortions are also risk factors. Tr. at 35.

On January 28, 1994, petitioner was nauseated and vomiting, which are symptoms of being pregnant. Tr. at 37. At that point, we do not know if the fetus was alive. *Id.* It is difficult to determine the age of a fetus when it is dying. Tr. at 37-38. Dr. Brent found it inconsistent that petitioner's last menstrual period was in November 1993, yet the embryo was a five-week size instead of an 8-10 week size. It should have been larger than five weeks. Tr. at 38-39.

Dr. Brent stated that an embryo in the fifth week of gestation is not in the all or none period. Tr. at 39. Early organogenesis is in the fifth week, not in the all or none period. *Id.* (Dr. Sindoni then stated petitioner's embryo was at two-week gestation at the time petitioner received MMR vaccine. Tr. at 39-40. The last menstrual period is a very subjective finding. Tr. at 44. Dr. Sindoni agreed that the embryo could already have been dead. Tr. at 45.) Dr. Brent stated that the CRL is accurate in a healthy pregnancy. *Id.* You cannot use the CRL in a dying embryo to determine when it was conceived. Tr. at 46. The uterine size continues to grow because it is under hormonal control. Dr. Brent thinks the conception occurred much earlier. *Id.*

Dr. Brent testified that in the all or none period, one could kill three of the eight cells of the embryo, and the remaining five cells can still form a normal embryo. Tr. at 52. If the MMR vaccine had killed petitioner's embryo at two weeks, it would not have grown to a five-week or 8-10 week size. Tr. at 53-54. (Dr. Sindoni then stated that after vaccination, over the next week or so, the rubella virus found its way to the embryo, and possibly more time elapsed before it had a cytopathic effect on the embryo. The timing could not be better for miscarriage. Tr. at 54-55.)

Dr. Brent testified that what Dr. Sindoni said was pure speculation. Tr. at 55. Dr. Brent stated that Dr. Sindoni forgot that petitioner was immune to rubella virus, having antibodies against rubella virus. Tr. at 55-56. Therefore, the rubella virus would not have been propagated. Tr. at 56.

Dr. Brent said to look at CDC reports: among 675 pregnant women who received rubella vaccine, not one had fetal abnormalities or problems. The abortion (miscarriage) rate was lower among the vaccinees than in the general population.. Tr. at 56. He contacted CDC several weeks before the hearing and got their latest report on 57 women who were immunized with rubella vaccine who were already immune, and, among that number, one pregnancy was lost. *Id.* (Dr. Sindoni then stated we do not know the exact strand of rubella virus so we do not know if petitioner was totally immune to rubella virus. Tr. at 58.) Dr. Brent stated that all rubella strains in the MMR vaccine protect against rubella. Tr. at 59. We could not use the vaccine if there were only one strain that was protective against rubella. Petitioner was immune to rubella regardless of the vaccine strain. *Id.*

For smokers, there is a 20% increase in the miscarriage rate. Tr. at 61. If petitioner had signs of rubella, she would have had fever, a headache, and rash. Tr. at 62. She had symptoms of pregnancy. *Id.* MMR does not cause miscarriage in an immune woman. Tr. at 65. Her fetus was not exposed to rubella virus at all because petitioner was immune. Tr. at 66. The rubella virus merely stimulated the production of antibodies. *Id.* The virus never reached the embryo. Tr. at 66-67. MMR vaccine is not advised for pregnant women because it contains live viruses. According to the CDC, the risk to a pregnant woman is almost zero. Tr. at 67. The HHS study does not deal with miscarriage. Tr. at 69.

Dr. Sindoni then said he had seen his own patients who were immune to rubella with rubella syndrome after receiving MMR vaccine. Tr. at 70. They had flu-like symptoms and joint pain. However, these women were not pregnant. Tr. at 70-71. Dr. Brent said there is no documentation of what these women had. Tr. at 71.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must offer "(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." Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

In Capizzano v. Secretary of HHS, 440 F.3d 1317, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...."

Close calls are to be resolved in favor of petitioners. Capizzano, supra, at 1327; Althen, supra, at 1280. *See generally*, Knudsen v. Secretary of HHS, 35 F.3d 543, 551 (Fed. Cir. 1994).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for MMR vaccine, she would not have miscarried, but also that the vaccine was a substantial factor in bringing about her miscarriage. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Petitioner's proof rests on the credibility of her expert, Dr. Sindoni, an obstetrician-gynecologist. The basis for his opinion on causation is the early stage of gestation and the MMWR which showed one spontaneous abortion (miscarriage) among 32 women who received rubella vaccine although they were previously immunized and were, thus, immune to adverse effects from rubella vaccine. From this one spontaneous abortion, Dr. Sindoni assumes causation, although the MMWR authors were silent on the topic. He agreed that the likelihood of petitioner's embryo being exposed to rubella virus from the MMR was reduced because petitioner had previously received MMR and was, thus, immune although he queried whether the rubella strain in the MMR she received was the same strain as in the MMR she had previously received. He admitted that the rate of spontaneous abortion among those 32 immune women was less than in the expected rate of spontaneous abortion in the general unvaccinated pregnant population.

Respondent's defense rests on the credibility of Dr. Brent, a living legend in the area of reproductive defects (teratology). He is without equal in the area of the risk of vaccination among the unborn. He was one of the founders of the Teratology Society and there is a

lectureship created in his name. He has published hundreds of articles, abstracts, and books. His opinion is that rubella virus in the MMR vaccine did not reach petitioner's embryo and kill it because petitioner was immune to the rubella part of the MMR vaccine from her prior MMR vaccination. He stated that it does not matter which rubella strain was in the earlier and later MMR vaccines. The strain protects against all rubella viral infection. The only effect petitioner's 1994 MMR vaccination would have had would be to produce antibodies in petitioner.

In choosing between these experts, the undersigned noticed Dr. Sindoni's lack of familiarity with the MMWR report he cited as supportive of his opinion. He thought there were 22 immune women, when there were 32. He thought the report concluded that rubella virus vaccine causes miscarriage when the report does not even discuss this. When faced with the four risk factors petitioner had, i.e., the MMR vaccine, her two prior miscarriages, her smoking, and her drinking, Dr. Sindoni picked the vaccine because petitioner had had three successful deliveries. But that leaves three miscarriages and three successful deliveries. In petitioner's case, she has a 50% chance of successful delivery, or one could say she has a 50% chance of miscarriage.

The undersigned holds that respondent's expert Dr. Brent is credible on the issues of this case while petitioner's expert Dr. Sindoni is not based on the training, experience, and expertise of Dr. Brent as compared to Dr. Sindoni, as well as the plausibility of Dr. Brent's opinion.

Petitioner's burden is to show a plausible medical theory and Dr. Sindoni's opinion is not plausible in the case of a woman previously immunized with MMR vaccine who receives another MMR vaccination. He recognized his opinion was less likely in this case but he could not

quantify the lessened likelihood. Lacking a plausible medical theory, Dr. Sindoni could not offer a logical sequence of cause and effect. Accepting, as the undersigned does, Dr. Brent's vastly superior understanding of fetal abnormalities and demise, there is nothing logical in assuming that rubella vaccine causes miscarriage when the vaccinee is immune to rubella. The only effect of the vaccine, according to Dr. Brent, was to produce antibodies in petitioner.

The real underpinning of Dr. Sindoni's opinion is the strong temporal relationship between the MMR vaccination and the embryo's demise. This is the third Althen prong. But satisfying the third prong without satisfying the first two Althen prongs does not satisfy petitioner's burden of proof.

Petitioner has not proved that but for MMR vaccine, she would not have miscarried and she has also not proved that MMR was a substantial factor in causing her miscarriage. Petitioner has not proved a prima facie case of causation.

CONCLUSION

This petition must be dismissed. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.[7]

IT IS SO ORDERED.

_____ _____

DATE Laura D. Millman
Special Master

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