In the United States Court of Federal Claims

No. 05-81V
(Filed: April 24, 2007)

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APRIL SPATES,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-1 *et seq*.; Motion to Review; Causation-in-fact; Measles-Mumps-Rubella Vaccine; Miscarriage or Spontaneous Abortion

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Thomas P. Gallagher, Somers Point, NJ, for petitioner.

Alexis B. Babcock, United States Department of Justice, Trial Attorney, Torts Branch, Civil Division, Washington, DC, with whom were *Peter D. Keisler*, Assistant Attorney General, *Timothy P. Garren*, Director, *Mark W. Rogers*, Deputy Director, and *Catharine E. Reeves*, Assistant Director, for respondent.

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OPINION

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BRUGGINK, *Judge*.

This is an action brought pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-1 *et seq*. (2000) ("Vaccine Act" or "Act"). The petitioner, Ms. April Spates, seeks compensation for injuries allegedly suffered as a result of the measles, mumps, and rubella ("MMR") vaccine she received while pregnant. Petitioner believes the MMR vaccine caused her miscarriage, which was discovered approximately one month after vaccination. Consequently, petitioner seeks compensation for the allegedly resulting emotional and physical injuries, including depression, embarrassment, and

bleeding. Initially, petitioner also sought an award for the death of her unborn child, but later withdrew that portion of her petition. A hearing was held on November 20, 2006, during which an expert for each party provided testimony relating to the causal connection, if any, between petitioner's MMR vaccination and her miscarriage. The petition was dismissed by the Special Master on January 31, 2007, for failure to demonstrate causation. *See Spates v. Sec'y of HHS*, No. 05-81V, 2007 WL 529716 (Fed. Cl. Spec. Mstr. Jan. 31, 2007). Shortly thereafter, petitioner filed a motion to review the decision of the Special Master pursuant to Rule 23 of the Vaccine Rules of the Court of Federal Claims ("Vaccine Rule"). The matter is fully briefed. For the reasons set out below, we sustain the decision of the Special Master.

BACKGROUND

Ms. Spates was born on November 22, 1967, in Brooklyn, New York City. On January 7, 1994, Ms. Spates received the MMR vaccine at the Fort Greene Health Clinic as a prerequisite for participation in classes at the College of New Rochelle, even though medical records reflect that Ms. Spates had already received the MMR vaccine as a child. Ms. Spates believed that she was not pregnant at the time. In an affidavit signed in August of 2005, Ms. Spates recalled feeling nauseated and weak, and suffering from headaches several days after receiving the vaccine. She also stated that she appeared pale and her ankles were swollen, making it difficult for her to walk.

On January 28, 1994, Ms. Spates traveled to Brookdale Hospital Medical Center in an ambulance because she was feeling drowsy and weak. A pregnancy test administered that day revealed that Ms. Spates was, in fact, pregnant. Ms. Spates returned to Brookdale on February 1, 1994, for follow-up testing. An ultrasound, or sonogram, was performed on Ms. Spates, which confirmed that she was pregnant. The procedure indicated that the crown-rump length ("CRL") of the embryo was 0.54 centimeters ("cm"). Based on the extent of the intrauterine growth, the doctor estimated that Ms. Spates had been pregnant for approximately eight to ten weeks. Thus Ms. Spates was pregnant on January 7, 1994, the day she was vaccinated.

The ultrasound revealed, however, that no fetal heartbeat was present. The doctor's examination notes mentioned MMR exposure under "diagnosis" and recommended a genetics test immediately and a repeat ultrasound the following day. Ms. Spates returned to Brookdale on February 4, 1994, for the repeat ultrasound. The second ultrasound confirmed the results of the first,

finding no fetal heartbeat. As a result, Ms. Spates requested to terminate her pregnancy due to the apparent miscarriage.

On February 8, 1994, Ms. Spates attended a scheduled appointment at the Brooklyn Hospital Medical Center for a dilatation and curettage ("D&C") procedure to remove the fetal tissue from her body. Ms. Spates was stable after the D&C procedure and showed no signs of vaginal bleeding.

According to medical records, in the years prior to her 1994 miscarriage, Ms. Spates received medical attention several times for both physical and psychiatric reasons. In November 1991, prior to the birth of her third child, Ms. Spates received a prenatal evaluation at the Interfaith Medical Center. During this evaluation, Ms. Spates acknowledged using cocaine, although the extent and frequency was not recorded. In June 1992, Ms. Spates was examined because she claimed entitlement to a social security disability due to a psychiatric disorder. The examination report noted, among other things, that Ms. Spates had smoked two and half packs of cigarettes each day for the previous five years. The doctor diagnosed Ms. Spates with depression and recommended follow-up care. During an examination in September 1992, Ms. Spates claimed for the first time that she had auditory hallucinations. In January 1993, Ms. Spates visited the Eastern Women's Center to terminate her sixth pregnancy. During this visit, Ms. Spates reported a history of anemia and excessive bleeding. She also reported a history of three live births, one miscarriage, and one abortion. Ms. Spates was discharged after the abortion procedure without complications. However, an ultrasound performed during the visit revealed the presence of an ovarian cyst, and Ms. Spates was advised to seek follow-up care.

In the years following her 1994 miscarriage, Ms. Spates received medical attention several times for vaginal bleeding and depression. For example, in May 1997, Ms. Spates was treated for two days of vaginal bleeding, prescribed ferrous sulfate, and then discharged from the hospital. In October 1997, Ms. Spates sought treatment for "urinary frequency" and was diagnosed with acute cystitis. In February 2001, Ms. Spates complained of continued vaginal bleeding that began five months earlier when she began using birth control. She was referred to a gynecologist and then discharged. In July 2001, Ms. Spates sought treatment for vaginal bleeding and was once again prescribed ferrous sulfate and discharged. In February 1999 and December 2001, Ms. Spates was treated for depression and prescribed antidepressant medications. During an examination in April 2002, Ms. Spates

explained that she had suffered from depression periodically since she was young. During this visit, however, she denied a history of drug abuse, denied having had hallucinations, and denied that she had been suicidal in the past. The doctor noted in the report that Ms. Spates was a poor historian and did not provide accurate information.

On November 30, 1995, Ms. Spates filed a medical malpractice lawsuit against, *inter alia*, the Fort Green Health Clinic and the doctor who administered the vaccine, in the Supreme Court of New York, County of Kings, seeking damages for the death of her unborn child and for various emotional and physical injuries. Ms. Spates alleged that she "became sick, sore, lame, swollen, disoriented, [and] bedridden," and that she suffered emotional distress in part because she was told that her life was in danger and that she "thought she was going to die" as a result of the vaccination. Pet'r's First Submission of Required Docs. at 15. The court dismissed the suit in its entirety on January 20, 2004.

Thereafter, on January 10, 2005, Ms. Spates filed a petition in this court seeking compensation under the Vaccine Act. Ms. Spates' first count alleged that as a "direct and proximate cause of the administering of the MMR vaccine, [she] sustained emotional and physical injuries, including . . . the death of her child in her womb, excessive and continued vaginal bleeding, depression and embarrassment." Pet. at 2. Ms. Spates' second count alleged that her unborn child died in her womb as a "direct and proximate cause of the MMR vaccine." *Id.*

On January 6, 2006, the Special Master issued an order to show cause why the request for death damages (i.e., the second count) should not be dismissed. *See Spates v. Sec'y of HHS*, No. 05-81V, 2006 WL 197316 (Fed. Cl. Spec. Mstr. Jan. 6, 2006). In that order, the Special Master explained that a petitioner seeking death benefits under the Vaccine Act must be the legal representative of the deceased. The Special Master also explained that under existing New York state law, "a lawsuit for death damages for a fetus is non-cognizable."[1] *Id*. at *2. As a result, Ms. Spates withdrew the portion of her

[1]The Vaccine Act explicitly allows the "legal representative of any person who died as the result of the administration of a vaccine" to seek compensation. 42 U.S.C. § 300aa–11(b)(1)(A). In the order to show cause, (continued...)

request related to the death of her unborn child, stating that "voluntary dismissal is warranted."[2] Pet'r's Attorney Certification. On February 2, 2006, the Special Master dismissed Ms. Spates as legal representative of her unborn child and allowed the case to proceed on the first count.

DECISION OF THE SPECIAL MASTER

In an opinion issued on January 31, 2007, the Special Master dismissed the petition for lack of causation. *See Spates*, 2007 WL 529716. The Special Master focused exclusively on the cause of the miscarriage. She primarily relied on the reports and testimony of two experts: Frank W. Sindoni, M.D., an obstetrician-gynecologist, for Ms. Spates, and Robert L. Brent, M.D., Ph.D.,

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[1](...continued)
the Special Master concluded that the law of New York "governs who has representative capacity to sue on behalf of a dead person" under the Act. *Spates*, 2006 WL 197316, at *3. The Special Master presumably based this conclusion on the Act's definition of "legal representative," which is defined as a "parent or an individual who qualifies as a legal guardian under State law." 42 U.S.C. § 300aa–33(2). Although we need not resolve the issue here, we observe the apparent ambiguity in this section – that is, whether a parent is a legal representative per se, irrespective of state law, or whether a parent must simultaneously qualify as a legal guardian under state law to be a legal representative under the Act.

[2]While we recognize that the dismissal of the second count of Ms. Spates' petition was "voluntary," and therefore is not before the court for review, we are troubled by the procedure involved. Although the order requests briefing on the standing issue, the Special Master stated in definitive and conclusive terms that Ms. Spates does not have representative capacity to seek death damages under the Vaccine Act and cannot prove representative capacity. The Special Master reminded petitioner's counsel that attorney fees are only recoverable upon a showing of reasonableness and good faith. In doing so, the Special Master stated that the "cognizability of that part of petitioner's petition in which she holds herself out to be her fetus's legal representative seeking death damages on behalf of her fetus is a matter of simple legal research." *Spates*, 2006 WL 197316, at *4. Perhaps predictably, petitioner's counsel did not brief the pertinent issue to the Special Master and consented to the immediate dismissal of a substantial portion of Ms. Spates' claim (i.e., the request for death damages).

D.Sc., a teratologist, for the government.[3] Both experts submitted reports to the Special Master and testified during a hearing on November 20, 2006, which was limited solely to the issue of whether the MMR vaccine caused Ms. Spates' miscarriage in 1994.

Dr. Sindoni testified that the MMR vaccine caused Ms. Spates' miscarriage. He explained that there was a logical sequence of cause and effect from the MMR vaccination administered on January 7, 1994 and the miscarriage that was observed nearly one month later. Dr. Sindoni based this conclusion on the gestational age of the embryo at the time of vaccination. He explained that the CRL, which he argued was a more accurate measure of embryonic age than the intrauterine growth, actually indicated that the embryo was only five weeks old when the ultrasound was administered in early February 1994, not eight to ten weeks as initially diagnosed. Dr. Sindoni thus concluded that the embryo was only two weeks old on January 7, 1994, the date of vaccination. Dr. Sindoni concluded that the embryo was exposed to the vaccine when it was very young, and thus, more susceptible to the vaccine. He argued that during this vulnerable stage, the rubella portion of the MMR vaccine can destroy the developing embryonic cells, resulting in a miscarriage. Dr. Sindoni relied on a Morbidity & Mortality Weekly Report[4] ("MMWR"), which he believed supported his theory that the rubella vaccine can cause miscarriage when administered during a woman's pregnancy. The MMWR examined data from the Vaccine in Pregnancy ("VIP") registry, maintained by the Center for Disease Control, which was a registry of women who received the rubella vaccine three months before or after conception. The outcomes of all pregnancies were tracked in the VIP registry. The MMWR evaluated the data to determine, among other things, whether pregnancy contraindicates the administration of the rubella vaccine because of the possibility of congenital rubella syndrome ("CRS") in infants. The MMWR showed that among 32 immune women who received the MMR vaccine while pregnant, one had a miscarriage.

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[3]Petitioner also submitted reports from Harold E. Buttram, M.D., a family physician, and Edward Black, M.D., a psychiatrist. The Special Master ultimately did not rely on either of these reports, and petitioner has raised no objections. Therefore, we need not review the substance of their reports here.

[4]*Rubella Vaccination during Pregnancy – United States, 1971–1988*, Morbidity & Mortality Wkly Rep., Vol. 38, No. 17, U.S. Department of Health & Human Services (May 5, 1989).

Dr. Sindoni believed that Ms. Spates' nausea in the weeks following the vaccination was due to her pregnancy and not the vaccine. Dr. Sindoni also explained that Ms. Spates' immunity to rubella decreased the likelihood that the rubella portion of the vaccine had an impact on the embryo, although he believed that it was still possible for the rubella to affect the embryo. Furthermore, Dr. Sindoni believed that certain factors, including Ms. Spate's history of smoking and prior miscarriages, increased the risk of miscarriage. He ultimately concluded, however, that the vaccine was the most likely cause of the miscarriage.

Dr. Brent, on the other hand, believed that the vaccine did not cause Ms. Spates' miscarriage. Dr. Brent based his conclusion primarily on Ms. Spates' prior immunity to MMR. He testified that, because Ms. Spates was already immune to MMR, the vaccine administered on January 7, 1994, would not have harmed her embryo. Not only was Ms. Spates already immune to MMR, Dr. Brent argued, there were other factors that increased her likelihood of miscarriage, including a history of miscarriages and a significant smoking habit. Dr. Brent explained that Ms. Spates' symptoms after January 7, 1994, were merely consistent with being pregnant, not signs of any ill-effect from the vaccine. Dr. Brent also insisted that there were no increased risks associated with the administration of the MMR vaccine to pregnant women.

Additionally, Dr. Brent challenged Dr. Sindoni's theory that Ms. Spates was vaccinated at a vulnerable stage of the pregnancy. He explained that the CRL is only an accurate measurement in a healthy embryo, not a dying or dead embryo. He argued, therefore, that it was impossible to determine the actual date of conception and, by extension, the age of the embryo at the time Ms. Spates received the vaccine. Even assuming the vaccine was administered at a point at which Ms. Spates had been pregnant for only two weeks, as Dr. Sindoni testified, then the embryo would not have grown to a CRL of 0.54 cm, which is the size of an embryo with a gestational age of approximately five weeks. Thus, Dr. Brent discounted Dr. Sindoni's belief that the vaccine was administered during the embryo's vulnerable age.

After considering the reports and testimony of the two primary witnesses, the Special Master concluded:

> [R]espondent'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.

Spates, 2007 WL 529716, at *14. The Special Master found Dr. Sindoni's theory of causation implausible because it did not adequately address Ms. Spates' existing immunity to the MMR vaccine, and, it was unsupported by scientific data. The Special Master believed that Ms. Spates had demonstrated a temporal relationship between the administration of the vaccine and the subsequent miscarriage, but no more. Accordingly, the Special Master concluded that Ms. Spates had not carried her burden of proof because she "has not proved that but for the MMR vaccine, she would have miscarried and she has also not proved that MMR was a substantial factor in causing her miscarriage." *Id.*

DISCUSSION

I. Overview

The Vaccine Act authorizes compensation to individuals for vaccine-related injuries or death. The Act provides two ways to establish causation. Causation is presumed when an individual's vaccine and injury falls within a prescribed time-frame set forth in the Vaccine Injury Table ("injury table"). *See generally* 42 U.S.C. § 300aa–14. If, however, an individual's vaccine and injury falls outside of the injury table, then that individual must affirmatively establish causation-in-fact. *See* 42 U.S.C. § 300aa–13(a)(1). Because Ms. Spates' alleged injuries do not fall within the prescribed injuries for the MMR vaccine in the injury table, she has the burden to establish causation-in-fact.[5]

It is now well-settled that a petitioner must satisfy, by a preponderance of evidence, three elements to establish causation-in-fact: "(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. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 1995).

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[5]With respect to the MMR vaccine, the injury table only encompasses anaphylaxis, anaphylactic shock, encephalopathy, encephalitis, and residual seizure disorder as the injuries entitled to a presumption of causation, none of which have been alleged by Ms. Spates.

The first two elements are related, in that 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." *Id.* (quoting *Grant v. Sec'y of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). The logical sequence of cause and effect can be supported by "evidence in the form of scientific studies or expert medical testimony." *Id.* The Federal Circuit has also explained that "neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." *Althen*, 418 F.3d at 1278. Ms. Spates must show "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of HHS*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999). Finally, these three elements "must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." *Pafford v. Sec'y of HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006).

II. Standard of Review

On a motion to review under Vaccine Rule 23, we may set aside findings of fact that are arbitrary or capricious, conclusions of law that are contrary to the law, and decisions that are an abuse of discretion. *See* 42 U.S.C. § 300aa–12(e)(2); *Walther v. Sec'y of HHS*, 69 Fed. Cl. 123, 126 (2005). When conducting our review, we give significant deference to the Special Master when determining the credibility and reliability of expert witnesses. *See Hanlon v. Sec'y of HHS*, 191 F.3d 1344, 1349 (Fed. Cir. 1999).

III. Decision of the Special Master Was Not Arbitrary, Capricious, Contrary to Law, or an Abuse of Discretion

Petitioner broadly objects to the Special Master's conclusion that she did not prove causation. Petitioner does not allege specific findings of facts or conclusions of law that were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. Instead, petitioner insists that through Dr. Sindoni's testimony alone, she satisfied all three *Althen* elements of causation. Petitioner appears to take the position that any medical opinion suffices to demonstrate causation-in-fact, irrespective of credibility, experience, and other medical data. Essentially, petitioner argues that because Dr. Sindoni offered a medical theory purporting to explain the cause of Ms. Spates' miscarriage, petitioner has satisfied her burden of proof. Respondent

argues that the "only basis for petitioner's appeal is her objection to credibility determinations made by the Special Master" and, therefore, petitioner's motion to review is merely an "effort to re-argue her case before this Court." Resp't's Resp. to Pet'r's Mot. to Review at 5.

We agree with respondent that the core of petitioner's motion to review is a challenge to the Special Master's credibility determination. Petitioner clearly believes that Dr. Sindoni's testimony was persuasive and should, therefore, be a sufficient demonstration of causation. Presumably then, petitioner believes that the Special Master, in rejecting the medical opinion of Dr. Sindoni, abused her discretion. We disagree.

The Special Master found Dr. Brent more convincing than Dr. Sindoni. Dr. Brent is a specialist in reproductive defects with a Ph.D in both embryology and biophysics. In his fifty-five years of practice, Dr. Brent has written extensively on reproduction and congenital defects, served on the editorial board of the *Birth Defects Journal*, and has served as a peer-reviewer on a variety of other related medical publications.[6] Dr. Sindoni, on the other hand, has been a general obstetrician-gynecologist in private practice for approximately twenty-five years. While we find no reason to question to Dr. Sindoni's general expertise, we believe the Special Master appropriately found his qualifications less relevant to the specific issue of the impact of the MMR vaccine during pregnancy. Additionally, the Special Master noted Dr. Sindoni's lack of familiarity with the MMWR he used to support his theory of causation. Notably, Dr. Sindoni drew conclusions from the report that were not, in fact, supported by the authors. *See discussion, infra*. Accordingly, we find no basis to question the Special Master's finding that Dr. Brent was more convincing than Dr. Sindoni, especially in light of our deferential standard of review. *See Bradley v. Sec'y of HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

With respect to the Special Master's decision on causation, we agree with the determination that only one of the three elements of causation were present. The temporal relationship between the vaccination and the discovery of the miscarriage is certainly consistent with petitioner's theory of causation, but, standing alone, does not amount to causation-in-fact. Petitioner has not

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[6]While we agree with the Special Master's favorable view of Dr. Brent, we disagree with the characterization that he is a "living legend" and "without equal." *Spates,* 2007 WL 529716, at *13.

presented any sound reason why the vaccine caused the miscarriage other than the temporal relationship.

Petitioner's medical theory under the first *Althen* element does not withstand scrutiny. Dr. Sindoni did not support his theory that the MMR vaccine can cause a miscarriage. Instead, he testified that it was *possible* for an immune woman to suffer a miscarriage when vaccinated during pregnancy and based that conclusion entirely on data from the MMWR. A chart in the MMWR reflected that 22 out of 683 women (immune or not) suffered a miscarriage after receiving the rubella vaccine. Of the 32 women who were immune to rubella (like Ms. Spates), only one suffered a miscarriage. From this data, Dr. Sindoni concluded that the rubella vaccine can cause a miscarriage. The authors of the report, however, never determined what caused the 22 miscarriages. In other words, the miscarriages could have been caused by any number of factors that were never considered in the report, including natural causes. Thus, Dr. Sindoni relied on a study that did not substantiate his medical theory connecting the vaccine to the miscarriage.

Moreover, the MMWR relied upon by Dr. Sindoni actually suggests there is no increased risk of miscarriage following vaccination. The objective of the report was to determine whether pregnancy is a contraindication to the rubella vaccination. Specifically, the authors of the report examined the data to determine whether vaccination increased the risk of CRS. After evaluating the data, the authors found "no evidence that the . . . rubella vaccine administered in pregnancy can cause defects indicative of CRS" and, therefore, risk of CRS following vaccination "continues to be zero." MMWR at 291. If the risk of CRS is "zero," then is it doubtful that the more severe injury (i.e., miscarriage) is anymore likely. Therefore, the MMWR indicates that the vaccine does not impact a pregnancy, irrespective of a woman's prior immunity. The Special Master appropriately found Dr. Sindoni less credible for his reliance on the MMWR. Dr. Sindoni did not present a persuasive medical theory causally connecting the vaccine to the miscarriage.

As to the second element of causation, petitioner's theory of a logical sequence of cause and effect was insufficient. Petitioner's theory was based on Dr. Sindoni's belief that Ms. Spates was vaccinated when her embryo was only two weeks old, which, he argued, is a developing embryo's most vulnerable age. Dr. Brent, however, questioned the plausibility of Dr. Sindoni's theory — if the embyro was at the critical age of two weeks on January 7, 1994, then it would not have grown to the size of a five-week-old

by early February 1994 if it was, in fact, killed by the vaccine. Assuming arguendo, however, that Ms. Spates was vaccinated at the vulnerable stage of her pregnancy, that fact alone is insufficient to show that the vaccine was the reason for the miscarriage. In fact, the authors of the MMWR concluded that there is no increased risk associated with the vaccine and pregnancy, which contradicts Dr. Sindoni's belief in a vulnerable or susceptible stage. Dr. Sindoni's testimony amounted to little more than an unsubstantiated possibility, which is far short of the standard required under *Althen*. Expert medical testimony must be credible, and in this case, it was not, because "an expert opinion is no better than the soundness of the reasons supporting it." *Perreira v. Sec'y of HHS*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994).

Finally, we believe petitioner failed to show causation for a more fundamental reason. A review of Ms. Spates' medical records suggests that her body was in substantially similar condition before vaccination as it was after. Ms. Spates had a pre-vaccination history of depression, vaginal bleeding, and miscarriages. Likewise, after January 7, 1994, Ms. Spates continued to suffer from depression and vaginal bleeding, and had one more miscarriage. Ms. Spates admitted to smoking heavily and using cocaine, which, as Dr. Sindoni acknowledged, increased the likelihood of having a miscarriage. Both Dr. Sindoni and Dr. Brent explained that Ms. Spates' symptoms of nausea and weakness in January 1994 were symptoms of pregnancy, not an adverse reaction to the vaccine. In short, we find nothing in the record that suggests something out of the ordinary occurred following Ms. Spates' vaccination. At most, the record reflects that the timing of Ms. Spates' vaccination and third miscarriage were coincidental.

In her motion to review, petitioner argues that the government failed to provide plausible theories of causation, suggesting it was the government's burden to disprove causation. Petitioner argues that "nothing in the record . . . can be definitively recognized as the cause of Petitioner's [miscarriage]." Pet'r's Mot. to Review at 8. The Vaccine Act only provides for compensation, however, when "*petitioner* has demonstrated by a preponderance of the evidence" that the vaccine caused the injury. 42 U.S.C. § 300aa–13(a)(1)(A) (emphasis added). Thus, the government had no obligation to explain what caused Ms. Spates' miscarriage. Petitioner is not entitled to compensation by default in the absence of an alternative explanation. Rather, petitioner must affirmatively demonstrate that the MMR vaccine caused her miscarriage, a burden petitioner failed to carry in this case.

CONCLUSION

For the reasons set out above, petitioner has failed to demonstrate that the decision of the Special Master was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. Accordingly, we sustain the decision of the Special Master, and deny petitioner's motion to review. The Clerk is directed to dismiss the petition.

s/Eric G. Bruggink
ERIC G. BRUGGINK
Judge