OFFICE OF SPECIAL MASTERS

No. 95-0716V

(Filed: March 15, 1999)

* *		
CHRISTINE HAYNES and KEVIN HAYNES, As Legal Representatives of KALYNN HAYNES, A Minor,	*	
Petitioners,	*	Publish
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *		

Andrew W. Dodd, Torrance, California, for petitioners.

Linda S. Renzi, United States Department of Justice, Washington, D.C., for respondent.

DECISION

WRIGHT, Special Master.

On October 27, 1995, petitioners filed a claim on behalf of their daughter, Kalynn, under the National Vaccine Injury Compensation Program (hereinafter "Vaccine Act" or the "Act").[(1)] Petition for Vaccine Compensation ("Petition"), filed October 27, 1995. Petitioners claim that as a direct result of a Measles-Mumps-Rubella (hereinafter "MMR") vaccination administered on June 29, 1994, Kalynn suffered chronic arthritis, which persists to this day. *Id.* at 2-3.

I.

PROCEDURAL BACKGROUND

On February 7, 1996, respondent filed a report in this matter recommending compensation be denied. Respondent's Report ("R. Rpt."), filed February 7, 1996. Respondent conceded that Kalynn's arthritis had

its onset within the Table time period of 42 days, and that her condition persisted for more than six months, as statutorily required. *Id.* at 5. However, respondent argued Kalynn's diagnosis of juvenile rheumatoid arthritis (hereinafter "JRA") statutorily prevented or *excluded* petitioners from demonstrating a Table injury, leaving a causation-in-fact claim the only available theory of recovery. *Id.* Respondent further submitted petitioners failed to demonstrate that the vaccination in question actually caused Kalynn's injuries since petitioners' expert's testimony and the literature failed to substantiate a causal relationship between the rubella vaccine and JRA in children. *Id.* at 6. An evidentiary hearing was held in this matter on September 23, 1997, and continued on January 20, 1998. Petitioners presented expert testimony from Dr. Deborah McCurdy at both hearings; Kalynn's mother, Christine Haynes, testified at the second hearing. Dr. Robert Lipnick testified on behalf of respondent at both hearings. The parties submitted their respective post-hearing briefs and the case is now ripe for a decision. Post-Hearing Brief of the Petitioners, Christine Haynes and Kevin Haynes, as Legal Representatives of Kalynn Haynes, a Minor ("P. Brief"), filed April 22, 1998; Respondent's Closing Argument ("R. Brief"), filed April 23, 1998.

II.

ISSUES TO BE DECIDED

The initial inquiry in this case is whether petitioners have demonstrated, by a preponderance of the evidence, that Kalynn suffered the Table injury of chronic arthritis as that injury is defined under the March 10, 1995, amendments to the Vaccine Injury Table. Before rendering a decision on this issue, however, I must resolve two sub-issues. First, does 42 C.F.R. § 100.3(b)(6)(ii), which excludes from the definition of chronic arthritis a diagnosis of JRA, govern (a) petitioners' initial burden to demonstrate a Table injury or (b) respondent's burden of proof under a "factor unrelated" defense? Second, did Kalynn suffer from juvenile rheumatoid arthritis or non-JRA chronic arthritis? Alternatively, and upon a finding that petitioners failed to demonstrate a Table injury, I must resolve whether the MMR vaccination Kalynn received actually caused her arthritic condition. After careful consideration of the evidence in this case, I conclude that petitioners failed to demonstrate, by a preponderance of the evidence, that Kalynn suffered a chronic arthritis Table injury, or in the alternative, that the MMR vaccine she received in June 1994 caused-in-fact her arthritic condition.

III.

FACTUAL BACKGROUND

The following evidence is contained in the record in this matter:[(2)]

Medical Records

Kalynn Haynes was born on April 12, 1993, after labor was induced due to a decrease in fetal

movements. P. Ex. 2 at 22. Kalynn's Apgar scores were noted at 9 at one and five minutes. *Id.*; P. Ex. 3 at 45, 46. The medical records reflect a normal physical examination and uneventful hospital course. P. Ex. 3 at 44. Kalynn's well-baby appointments noted overall a healthy infant, with occasional incidences of spitting up, loss of appetite, restlessness, fussiness, diarrhea, and ear rubbing. P. Ex. 10 at 193, 196-199, 201. On June 22, 1994, Kalynn was examined for complaints of fussiness, drooling, and loss of appetite; Kalynn was thought to be teething. *Id.* at 202. One week later, on June 29, 1994, Kalynn received her MMR and HiB vaccinations, in the left arm and left thigh, respectively. *Id.*; P. Ex. 11 at 209. The administering physician noted at the time that "[n]o problems [were] voiced" regarding Kalynn's health. P. Ex. 10 at 202.

A telephone message recorded July 1, 1994, two days after the vaccination, indicated Kalynn refused to walk and fussed with standing.[(3)] *Id.* at 203. A July 18 telephone call from Mrs. Haynes indicated Kalynn was experiencing pain in her left hip when being assisted from her crib and during her diaper changes. *Id.* at 206. Dr. Chang T. Lin reported, during Kalynn's appointment that same day, a three week history of left hip pain. *Id.* at 205. His examination revealed no redness, swelling, tenderness, or limitations of the hip joints, knees or ankles. *Id.* He also noted that Kalynn was limping, but he did not know the cause. *Id.* Dr. Joel A. Streng's record from an appointment conducted on or before July 22[(4)] states:

Pt. [patient] is referred . . . for evaluation due to some persistent apparent pain in the left hip and also some limping over the past 3-4 weeks. About 1 month ago the Pt. [patient] got an MMR on the left thigh area. One week later the mother noted that she started to have some pain with movement of that left hip area and sometimes with pressure in the left hip area when she was changing her diaper. She started limping to some degree over the next few weeks and then about 4-5 days ago she would not stand when she first woke up in the morning. As the day went on she started walking but then after each nap also she would not stand for a period of time. When she started walking she would seem to do fine. She has had no fever.

P. Ex. 17 at 346. On July 30, Kalynn was unable to stand and suffered from hip pain. P. Ex. 14 at 212. A telephone call from Kalynn's mother on August 1, 1994, indicated Kalynn had experienced severe pain over the weekend. P. Ex. 17 at 347. Kalynn was thereafter admitted on August 1, 1994, to Children's Hospital of Orange County, to rule out discitis. P. Ex. 4 at 48. Kalynn's admission record described her symptoms and onset as follows: "5-6 wks. of limping, decreased ambulation, decr. [decreased] sleeping, [and] incr. [increased] irritability." *Id.*

During Kalynn's hospitalization, several different physicians documented Kalynn's prior history and onset of her illness, some specifically and others generally. Dr. Habib Ismail's neurology evaluation of August 1, 1994, recorded that two days after the vaccination Kalynn limped on her left side and her left thigh and buttock muscles were tender to the touch, although there was no evidence of redness, bruising, or swelling.[(5)] P. Ex. 18 at 366. In the following two weeks, Kalynn exhibited mild limping, although he noted the parents were unsure whether Kalynn was just unstable in her toddler walk. *Id.* In addition, Kalynn "would cry and fuss" intermittently "as if in pain" when her mother "would change her diaper and bend her left leg up." *Id.* By July 18, Kalynn was in significant pain, with obvious limping; she refused to permit movement of her left hip and her parents sought medical attention. *Id.* at 367. Thereafter, her parents noted a progressively worsening condition. *Id.* Dr. Ismail wrote:

They [Kalynn's parents] report her to be having episodes of pain, which can last up to four hours. She will roll over on the floor for about 10-15 minutes and does not allow her mother to hold her up. Her legs seem stiff and in pain. When in pain, she wants to be laying on the floor face down in the prone position. Her mother points out that Kalynn has always slept on her back until her current symptoms. She is sleeping now in a peculiar position with her face down and her hip protruded to one side. During the pain

episode, she does not want to bear weight on her feet. In between pain episodes, she has been walking. The pain episodes may last from 10 minutes to four hours. Lately, there are getting long. A hot bath seems to help symptoms. After a pain episode when she starts walking, initially she has a stiff legged walk for a few minutes, and then she will walk with limping on the left side until the next episode. She has been having daily episodes day and night and she has been up at night every two hours for the last week.

Id.

The history taken for Dr. Jeffrey Dobyns on August 1, 1994, reported Kalynn exhibited a "progressive limp & fussiness since [the] beginning of July. Pt [patient] started to limp following immunizations." Tr. Ex. at 1. It further notes a negative history for fevers or chills. *Id.* Dr. Dobyns' August 2 record documented a slightly more detailed history following a discussion with Mrs. Haynes. *Id.* at 3. He noted Kalynn had intermittent fevers for the past four weeks and limping since the immunization. *Id.* The limp "worsened" until July 22 when Kalynn refused to walk. *Id.*

An infectious disease consult note, dated August 2, 1994, reported Kalynn as limping and having stiffness and tenderness in the left thigh muscle on June 30, 1994, one day after the vaccination. *Id.* at 5. Thereafter, Kalynn's condition "progressively worsened with pain on flexing thigh for [change] of diaper [with] pointing to [left] groin."(6) *Id.* The entry then states Kalynn's "[p]ain worsened significantly on 7/28" when she experienced "[decreased] walking especially early morning and [increased] during day." *Id.* The physician further reported on Kalynn's condition: "Wakes up around 3 AM, thrashing around seemingly unable to find a comfortable position and crying . . . inability to stand up without "tiptoeing" or pulling up to stand. Child has had intermittent fevers during this episode. Seems more at night. Max 101 F." *Id.* The physician further noted a possible positive bone scan at L2. *Id.* at 6.

Dr. McCurdy first examined Kalynn on August 7, 1994. Her notes from that consultation show that in the several days following Kalynn's vaccination, she was "unable to stand on [her] leg." *Id.* at 20. This progressed "[o]ver the week [such that Kalynn was] unable to walk on [her][left] hip"; this then "got worse over the next week." *Id.* Dr. McCurdy further described Kalynn's prior history: "Third/4rth week after shot--wouldn't stand/sit play. Fourth week--awake screaming--hot back legs--severe pain . . . By 5th week--drop to floor quickly. Refuses to walk--Very stiff. Admitted to CHOC 8/1 for severe pain--in both hips/lower back . . . Had fevers 100-100.5--off & on since vaccination." *Id.*

Prior to her admission to Children's Hospital in August 1994, petitioners sought treatment for Kalynn's condition on July 18, 1994. Follow-up examinations and tests revealed a normal lumbar spine and a normal MRI of Kalynn's left hip. P. Ex. 14 at 215; P. Ex. 15 at 242; P. Ex. 20 at 376. Kalynn's radiological scan of her pelvis and hips also returned negative. P. Ex. 15 at 241. At the end of July, further tests were conducted immediately prior to her hospital admission. Kalynn's whole body bone scan conducted July 28, 1994, revealed:

1. No definite evidence of septic joint arthritis in the left hip. 2. There is slightly increased activity in the region of L2 seen on the anterior view not confirmed on the posterior view. However, repeat images to the same area could not be performed because the patient was awake and was moving during the acquisition. Recommend x-ray correlation if there is any clinical suspicion.(7)

P. Ex. 14 at 226, 228. Pelvic and abdominal ultrasounds conducted July 30 returned negative and unremarkable. *Id.* at 233, 234.

Upon her admission on August 1, Kalynn was diagnosed with acute pain, etiology unknown. P. Ex. 4 at

50, 51. While hospitalized, Kalynn developed a rash and high fever on or about August 4, 1994, which persisted for several days. *Id.* at 66, 72-74, 78, 81-82, 87, 91, 95, 100, 102; Tr. Ex. 12-21, 25. Kalynn's rash and fever were attributed to hospital-acquired aseptic meningitis. P. Ex. 4 at 122; Tr. Ex. at 18. An entry from Dr. David Lang, an infectious disease physician, states "At present I view this as two distinct processes: a) post immunization some sort of toxic synovitis or perhaps--tho[ugh] unusual in this age group--an arthralgia/arthritis related to rubella, b) fever, rash, CSF pleocytosis reflects a [illegible] acquired viral infection." Tr. Ex. at 18. Dr. Levin, Kalynn's neurologist, concurred with Dr. Lang's assessment that Kalynn was experiencing two different problems. *Id.* at 19. Kalynn underwent extensive testing while at Children's Hospital to rule out numerous possible explanations for her condition. P. Ex. 4 at 121-122. Laboratory tests confirmed a positive antinuclear antibody ("ANA") screen at 1:320. P. Ex. 8 at 164. Kalynn's rubella results from cerebrospinal fluid collected August 25, 1994, returned initially at 3.0 for Rubella IgG and negative for Rubella IgM; later results returned negative for Rubella IgG and Rubella IgM. *Id.* at 163, 164, 166. Kalynn's EMG/Nerve Conduction Velocity tests were considered normal (although the exam was limited to the left lower extremity) as were her waking and sleeping EEG. P. Ex. 9 at 186, 187; P. Ex. 38 at 422. Kalynn's MRIs of the cervicothoracic spine, thoracolumbar spine and brain were also normal. P. Ex. 19 at 372-374. The whole body tumor study showed "no scintigraphic evidence of discitis of the lumbar spine." *Id.* at 375. Kalynn remained hospitalized until August 8, 1994, when she was discharged with diagnoses of post-immunization rheumatologic condition and hospital-acquired aseptic meningitis. P. Ex. 4 at 121-122.

Following Kalynn's discharge, her condition and diagnosis were discussed in correspondence between her doctors. Dr. Streng's September 8, 1994, letter to Dr. Constance Corsino states in its addendum: "Presently, it is felt that her problems are related to her recent MMR, especially the Rubella part of her MMR. She is having further studies performed related to this by Dr. Cherry at UCLA, in addition. Hopefully we will be able to make a firm diagnosis once this is performed in the best interest of this child who has been going through difficult times." P. Ex. 17 at 354. Dr. Streng's second addendum, dated September 30, then notes: "Upon discussion with Mrs. Haynes on September 30, 1994, Kalynn's present diagnosis is felt to be that of Juvenile Rheumatoid Arthritis." *Id.* at 355. In various letters written by Dr. McCurdy and Dr. Sanematsu to Kalynn's other physicians, it is noted that Kalynn developed irritability, arthritis, and severe joint pain/myopathy ten days to two weeks after her vaccination which increased to severe pain and a refusal to walk by July 31, 1994. P. Ex. 5 at 124, 128, 131.

Dr. McCurdy diagnosed JRA (including pauciarticular and polyarticular[(8)]) consistently nearly every month from September 1994 through February 1996 and July 1996 through September 1996. P. Ex. 6 at 141, 147-153; P. Ex. 38 at 435, 477, 482, 485, 488, 490, 508, 511, 515, 516, 518, 530, 533, 535. Dr. McCurdy explained the bases for her diagnosis in letters to Kalynn's other physicians:

[Kalynn] has quite a complex course, initially thought to be due to a rubella vaccination. *However, as the joint pain and swelling has persisted, I think that it is more likely that she has a pauciarticular type of juvenile rheumatoid arthritis . . . I think that the most likely diagnosis at this time is pauciarticular juvenile rheumatoid arthritis, particularly in view of the positive ANA which was obtained at the time of the last blood work. Her ANA was 1:320.* Although this could have been triggered by the rubella vaccination, *I think that this has persisted for too long to be strictly a post rubella vaccination synovitis. We therefore discussed with the parents a pauci-articular juvenile rheumatoid arthritis.*

P. Ex. 5 at 126-127 (September 14, 1994, letter to Dr. Corsino) (Emphasis supplied). In her October 17, 1994, letter to Dr. Streng, Dr. McCurdy submitted Kalynn "has a diagnosis of polyarticular juvenile rheumatoid arthritis . . . [and] *fairly clearly falls within the range of a polyarticular juvenile rheumatoid arthritis*." *Id.* at 128-129 (Emphasis supplied). In contrast, in several of Dr. McCurdy's later Rheumatology Visit chart notations and letters, she reverted to a diagnosis that relates Kalynn's arthritis to her past rubella shot.[(9)]

Incidentally, Dr. McCurdy filed a Vaccine Adverse Event Reporting System (VAERS) report on November 23, 1994, which described Kalynn's symptoms, treatment, and diagnosis as "Pain in legs, back, irritability, viral meningitis--R/O [rule out] discitis. Admitted Aug 1-8, 1994. Txed for viral meningitis--Arthritis of knee--ANA [medical abbreviation for "positive"] 1:320. Probable JRA-polyarticular." P. Ex. 12 at 210. Dr. McCurdy referenced July 26-27, 1994, as the date of onset of Kalynn's symptoms. *Id.*

Mrs. Christine Haynes' Affidavits

Mrs. Haynes filed two affidavits in this case. The first accompanied the petition while the second was appended to a contemporaneous calendar which notes Kalynn's condition on certain days in June and July 1994. Petition at Exhibit A ("Petition Aff."); Submission of Contemporaneous Calendar, filed December 11, 1995, at Exhibit A ("Calendar Aff."). The statements contained in the affidavit attached to the calendar coincide with the notations written on the calendar and provide a brief explanation of the notations. Jointly, these affidavits describe Kalynn's symptoms beginning June 30, one day after the shot, when she experienced a cramp or charlie horse. Petition Aff. at 2; Calendar Aff. at 2. By July 5, she was limping, fussy, and not improving. *Id.* This continued on July 7, when Mrs. Haynes noticed her daughter favoring one leg. Petition Aff. at 2. By July 9, Kalynn ceased routine walking and refused to bear weight. *Id.*; Calendar Aff. at 3. Mrs. Haynes did not specifically describe any further worsening after July 9, but attested that within thirty days Kalynn developed chronic joint symptoms with pain, multiple joint swelling, and limitation of motion. Petition Aff. at 2-3.

Mrs. Christine Haynes' Hearing Testimony

Mrs. Haynes' hearing testimony explains more fully Kalynn's condition, although it appears she ultimately relies on her affidavits as representing the true picture of her daughter's symptoms where her testimony conflicts with the affidavits. Mrs. Haynes testified Kalynn was crying and irritated on June 30, the day after her MMR vaccination. Tr. at 125, 126. She had a charlie horse or cramping and stiffness in her left hip and left leg. *Id.* She did not want to crawl or walk or stretch or move her left hip region. *Id.* at 126. She favored her left hip and leg, limped while walking, and utilized the furniture to help her bear her weight. *Id.*

Mrs. Haynes then described both an improvement in and yet continuation of Kalynn's condition between June 30 and July 4. She described Kalynn as happy and bearing weight and agreed Kalynn was "totally back to normal," moving as she did before the vaccination. *Id.* at 127-128. Discomfort during diaper changes occurred only in the first week. *Id.* at 138. However, at other times she also characterized her daughter as still limping and favoring her left leg and later conceded Kalynn was not back to normal. *Id.* at 127, 131, 132, 133, 138.

Mrs. Haynes' testimony regarding Kalynn's condition July 5, July 7, and July 9 parrots her affidavits. *Id.* at 128, 131-133, 139. Mrs. Haynes also testified Kalynn's limping began within two days of her shot and continued, mildly, for 2 weeks thereafter. *Id.* at 140. However, Mrs. Haynes again described Kalynn in conflicting terms with respect to her July 18 condition. She stated Kalynn's behavior did not change dramatically, but described an increasingly fussy, frustrated, and crying child with apparent pain in the hip and a more noticeable limp. *Id.* at 129, 130, 132-133, 137, 138. Mrs. Haynes further testified Kalynn's condition worsened in the weeks following July 18, resulting in her hospitalization August 1, 1994. *Id.* at 134, 137. As Mrs. Haynes stated, Kalynn's arthritis persists to this day; this is uncontested. *Id.* at 134-137.

IV.

EXPERT TESTIMONY

Dr. Deborah McCurdy

Petitioners presented the testimony of Dr. Deborah McCurdy, a practicing pediatric rheumatologist and Kalynn's principal treating physician for her rheumatoid problems.(10) Dr. McCurdy's testimony was confusing and conflicting, at best. However, after a careful review of her testimony and expert reports, I have concluded Dr. McCurdy rendered two opinions. First, she opines more probably than not, that the rubella vaccine triggered Kalynn's chronic arthritis and that Kalynn's arthritic condition, as it became chronic, followed a course expected in JRA patients. Tr. at 22, 172, 176, 178. Second, she cannot opine to a reasonable degree of medical certainty, or more probably than not, that Kalynn's arthritic condition *is* or *is not* JRA. *Id.* at 39, 40, 172-173, 176.

(1) Chronic arthritis related to the rubella vaccination: Dr. McCurdy testified that chronic arthritis in children is not well defined, but patients may experience, *two to six weeks after the rubella inoculation*, the following symptoms: rash, low grade fever, polyarthralgias (joint pain), arthritis (joint swelling), myalgia, paresthesia, and multiple joint involvement. *Id.* at 17, 18, 19, 43, 171. She further testified the reaction is typically self-limited, lasting several months then resolving.(11) *Id.* at 18. However, she also noted some patients' arthritic conditions may last several years, and in a small percentage, become chronic. *Id.* at 18, 43. Dr. McCurdy bases her opinion that Kalynn's condition is vaccine-related principally on her belief that Kalynn's arthritic symptoms began within the time period expected for rubella vaccine reactions, on or about July 18, 1994, when she developed a rash, fever, and significant, worsening pain in her joints and lumbar region. P. Ex. 31 at 2, 3; P. Ex. 31a at 1; P. Ex. 31b at 1; Tr. at 16, 47, 48-49, 50, 153, 178. Dr. McCurdy explained that the symptoms Kalynn experienced 24-48 hours to two weeks following the vaccination evidenced simply a temporary local reaction, *i.e.*, muscular pain in the left hip, thigh, and buttock at the injection site, unrelated to her arthritis. P. Ex. 31 at 1; Tr. at 46-47, 48, 49, 70-71, 116, 117. Dr. McCurdy's relies on the parents' statements that Kalynn's muscle pain resolved, she returned to normal, and then two weeks later Kalynn experienced joint pain. Tr. at 47. Dr. McCurdy further believes Kalynn's condition changed around July 18, 1994, when according to a history provided by her parents, Kalynn's pain moved from the left hip and thigh muscles, the situs of the inoculation, to her joints and back. *Id.* at 46-49, 66, 70-72. She further testified that she knew Kalynn's pain was different on or about July 18, 1994, based on the parents' description that Kalynn had discomfort during her diaper changes. *Id.* at 49.

Dr. McCurdy strongly believes Kalynn's presentation was atypical for JRA.(12) *Id.* at 12-14, 16, 22, 27, 28, 30, 34, 35, 39, 40, 162. She emphasized that Kalynn's condition was temporally associated to the rubella inoculation and that Kalynn experienced hip pain contrary to the expected JRA picture. *Id.* at 12, 16. She further relies on Kalynn's stiff, lordotic(13), antalgic(14) gait, and the July 28, 1994, bone scan as evidence of initial spinal/lumbar pain and arthritis in the back, which would be atypical for JRA.(15) *Id.* at 12, 16, 38, 55, 104, 105, 106, 114, 156, 160; P. Ex. 31 at 2. She claimed Kalynn's rash presented differently and lasted longer than would be expected in JRA patients where rashes "come[] and go." Tr. at 12, 17, 50. Instead, Dr. McCurdy attributed Kalynn's rash and fever, pursuant to the literature and her initial contacts with the infectious disease staff, to a post-rubella picture. P. Ex. 31 at 3; P. Ex. 31a at 1; Tr. at 50, 151, 170-171. She testified the rash occurred, as expected, within 20 days after the shot, lasted for a couple of days, and "looked like a viral rash . . . and probably is typical of what you could see with rubella." Tr. at 50. Dr. McCurdy also believes Kalynn suffered less swelling ("dry arthritis") and less exacerbations and remissions than would be expected in pauciarticular JRA. *Id.* at 13, 14, 38, 155-156. Finally, she claimed Kalynn exhibited a high degree of irritability and asymmetrical presentation of multiple joint (lower back, left hip, one knee) involvement, again contrary to the typical presenting picture expected in JRA patients.(16) *Id.* at 12-13, 16, 17, 55-56, 158, 162.

Dr. McCurdy insisted Kalynn's condition was considered post-infectious or post-vaccinal arthritis from the beginning. *Id.* at 28, 47-48, 51, 151, 153. She testified she relied on the infectious disease physicians' expertise that the rubella vaccine caused Kalynn's illness; other illnesses, such as discitis and a malignancy (leukemia) were ruled out. *Id.* at 28, 51, 153, 159. Dr. McCurdy emphasized the temporal proximity of Kalynn's arthritic onset to the vaccination and stated the medical literature supports a causal link between the rubella vaccination and chronic arthritis in children. *Id.* at 16, 29-33, 166, 175; P. Ex. 31 at 3-4; P. Ex. 31a at 1-2; P. Ex. 31b at 1-2. Dr. McCurdy recognized that the rubella virus was not isolated during testing; she explained isolation is difficult, no testing was conducted during Kalynn's acute onset, and a negative result does not rule out a rubella association. Tr. at 51-53, 167. She also admitted she has only seen five to ten post-vaccinal pediatric cases over the past 6-10 years of her career. *Id.* at 42. Kalynn is also her *only patient to have a chronic condition*, which Dr. McCurdy agreed makes Kalynn's post-vaccinal arthritis atypical. *Id.* at 43.

(2) Juvenile Rheumatoid Arthritis: Dr. McCurdy explained her inability to accept or reject JRA as a "semantics" quandary because JRA's cause is unknown.[(17)] *Id.* at 15, 23, 30, 34, 39-40, 172, 176. She testified any type of chronic arthritis may be termed JRA, thus implying a vaccine-related case may also be labeled JRA. *Id.* at 23, 30, 40, 42. While Dr. McCurdy diagnosed Kalynn with pauciarticular JRA, and later with polyarticular JRA, she testified she wrote JRA in the charts because the cause of Kalynn's condition was unknown. *Id.* at 22, 34, 115, 162, 163-164.[(18)] She now feels the presentation was atypical for pauciarticular JRA and prefers a diagnosis of chronic arthritis or chronic arthropathy. *Id.* at 27, 39, 40, 115, 162. Although she initially considered but rejected the vaccine's role and then diagnosed JRA, her review of relevant literature changed her opinion to a finding of post-vaccinal arthritis. *Id.* at 29, 30-31, 41. Dr. McCurdy conceded Kalynn's presentation met a strict interpretation of the JRA criteria and that her current course and treatment is consistent with or not unlike that found in polyarticular JRA patients. *Id.* at 14, 35, 170, 172, 178; P. Ex. 31b at 1-2. Dr. McCurdy also posits the rubella virus may possibly initiate JRA, although she also testified the articles she submitted do not link the vaccine to chronic arthritis in children. Tr. at 45, 164. *See also* P. Ex. 28, 29, 32, 33a, 34, 35.

Dr. Robert Lipnick

Dr. Robert Lipnick, also a pediatric rheumatologist, testified on respondent's behalf.[(19)] Dr. Lipnick opined, more probably than not, that Kalynn's arthritis is JRA and that her current condition, as described by Dr. McCurdy at the hearing, is a sequela of her arthritis and typical of JRA. Tr. at 80, 96, 98-99, 100. He believes that the onset of Kalynn's arthritic condition occurred within one to two days following her vaccination, when she demonstrated irritability, discomfort, difficulty with her left leg, and cessation of walking, which ultimately progressed, albeit intermittently at times, and escalated in the subsequent five weeks. *Id.* at 143, 180. Dr. Lipnick relied on Kalynn's limping and unwillingness to walk on July 1, 1994, as evidence of joint pain. *Id.* at 82-83. He further believes the intermittent nature of her signs and symptoms over the subsequent weeks was very suggestive of JRA. *Id.* at 84, 180. He rejected the notion that Kalynn's early symptoms represented a local situs reaction. *Id.* at 83, 101. In his opinion, a local reaction is uncommon with hip vaccines and, in any event, the symptoms in such cases last only a few days, not more than a week. *Id.* In addition, redness would be expected with the degree of pain experienced in this case. *Id.* at 83. In sum, Dr. Lipnick believes the symptoms Kalynn experienced in the few days following her vaccination represented the onset of her arthritic condition and that these symptoms progressed until her July 18th doctor's visit. Moreover, Dr. Lipnick testified the arthritic symptoms which Kalynn suffered immediately following her inoculation manifested too early to be vaccine-related. *Id.* at 83, 183. Dr. Lipnick testified Kalynn's rubella titer results do not support that she sustained a recent infection with the rubella virus; he would expect a "more prominent response by her immune system." *Id.* at 88.

Dr. Lipnick finds Kalynn's onset typified a pauciarticular JRA presentation, fitting the JRA criteria set forth by the American College of Rheumatology. *Id.* at 80-81, 91, 116, 180. Not surprisingly then, Dr. Lipnick also finds Dr. McCurdy's bases for finding an atypical presentation of JRA unsupported.[(20)] He testified Kalynn presented as expected with pauciarticular JRA patients; she experienced asymmetrical multiple joint involvement, swelling, tenderness, morning stiffness, limitation of motion of the joints, exacerbations and remissions over the past three years, and a positive ANA, which Dr. Lipnick testified occurs in 30-40% of pauciarticular cases.[(21)] *Id.* at 81, 84-86, 89, 100, 143-144. He further noted 5-10% of JRA patients have dry synovitis. *Id.* at 86-87. He related Kalynn's fever and rash to either hospital-acquired aseptic meningitis or to a viral infection incurred in the days prior to her hospitalization, not to her arthritic picture. *Id.* at 116, 145, 146, 180. He believes Kalynn's rash and fever were unrelated to the rubella vaccine since these symptoms occurred beyond the time frame expected in rubella-related rashes, which is usually ten days to two weeks after the vaccination. *Id.* at 89, 147; R. Ex. A at 2. Dr. Lipnick also testified the evidence in the records does not support a finding of arthritis in the hips or back. Tr. at 81, 109-111, 142, 180-181. Dr. Lipnick further opined Kalynn's course is consistent with that expected in pauciarticular JRA cases which progress to polyarticular JRA. *Id.* at 143, 181; R. Ex. A at 1, 2. In contrast, Dr. Lipnick testified a reactive arthritis patient's condition lasts a few days, occasionally two to three weeks, then resolves. Tr. at 144.

Dr. Lipnick testified the general role of the MMR vaccine or viral infections in the development of JRA or chronic arthritis is speculative; he further believes "Kalynn had a genetic predisposition and underlying immune abnormalities favoring the development of JRA." R. Ex. A at 2; Tr. at 182-183. He agreed the etiology of JRA is unknown, and that it "appears to be multi-factorial in etiology involving immunogenic predisposition, autoimmunity, infection, trauma and/or stress." R. Ex. A at 2; Tr. at 98. However, he also testified that rubella-induced arthritis, by definition, is not JRA. Tr. at 94. Dr. Lipnick is unaware of any literature linking the onset of JRA with the rubella vaccine. *Id.* at 89.

V.

DISCUSSION

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation, or by proving causation in fact. Petitioners must prove one or the other in order to recover under the Act.[(22)] A discussion of petitioners' Table injury and causation-in-fact claims follows.

Table injury

As outlined above, before I can decide if Kalynn suffered a Table injury, I must resolve two sub-issues. First, does the exclusionary provision in 42 C.F.R. § 100.3(b)(6)(ii) govern (a) petitioners' initial burden to demonstrate a Table injury or (b) respondent's burden of proof under a "factor unrelated" defense? Second, did Kalynn suffer from juvenile rheumatoid arthritis or non-JRA chronic arthritis? These issues are analyzed in turn below.

(1) Does the exclusionary provision in 42 C.F.R. § 100.3(b)(6)(ii) govern (a) petitioners' initial burden to demonstrate a Table injury or (b) respondent's burden of proof under a "factor unrelated" defense?

The Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition.[(23)] The Table lists chronic arthritis as a compensable injury which creates a presumption of causation if the onset of the chronic arthritis occurs within 42 days of the administration of the MMR vaccine.[(24)] Once a Table injury

has been established by a preponderance of the evidence, the presumption of vaccine-relatedness may be overcome by an affirmative showing that the injury was caused by a factor unrelated to the administration of the vaccine.[25]

Chronic arthritis was added as a new Table injury for the MMR vaccine pursuant to the administrative revision of the Table, promulgated on March 10, 1995. *See* 60 Fed. Reg. 7678 (1995); 42 C.F.R. § 100.3 (a)(II)(b)(A) and § 100.3(b)(6). The amendment states chronic arthritis "may be found in a person with no prior history of arthropathy (joint disease)." 42 C.F.R. § 100.3(b)(6)(i). The basis for this finding may be:

(A) [m]edical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred within 42 days after a rubella vaccination; and

(B) [m]edical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination.

Id. However, the revised Table explicitly excludes JRA as a presumptively vaccine-related chronic arthritis Table injury. *The Table revision provides that juvenile rheumatoid arthritis, among other conditions, "shall not be considered as chronic arthritis."* 42 C.F.R. § 100.3(b)(6)(ii) and (iii) (Emphasis supplied).

Petitioners claim Kalynn suffered chronic arthritis within the Table time period following her MMR vaccination, and that this condition persisted for more than six months. Petition at 2-3, 7; P. Brief at 2-3. Therefore, petitioners argue they have established a rebuttable presumption and the burden now shifts to respondent to prove a factor unrelated to the administration of the vaccine caused Kalynn's injury. P. Brief at 4, 5. Petitioners further contend their case withstands respondent's factor unrelated proof. Specifically, relying on § 13(a)(2)(A) of the Act, petitioners submit that respondent's claim, that JRA is the factor unrelated, fails since the etiology of JRA is unknown and, statutorily, a factor unrelated may not be idiopathic or of unknown cause.[26] *Id.* at 3, 6, 7, 12-13. In the alternative and upon a finding by the undersigned that Kalynn has JRA, petitioners claim, primarily through their expert's testimony, that the rubella vaccine actually caused Kalynn's juvenile rheumatoid arthritis. P. Brief at 6, fn. 3; Petition at 3; Tr. at 164.

Respondent concedes Kalynn suffered arthritis within 42 days following her MMR vaccination, which continued for at least 6 months thereafter, but argues Kalynn suffers from JRA which may not be considered, pursuant to the statutory language, as Table chronic arthritis. R. Rpt. at 5; R. Brief at 1, 2-3, 12. Thus, respondent contends petitioners' Table claim fails, leaving actual causation as their sole theory of recovery. R. Rpt. at 5; R. Brief at 3. In essence, respondent submits petitioners failed to make a *prima facie* case; therefore, the factor unrelated analysis never arises. R. Brief at 3. Respondent further charges that petitioners failed to prove that the rubella vaccination actually caused Kalynn's JRA. *Id.* at 1; R. Rpt. at 6.

Petitioners present an interesting, but not novel, legal issue. Special Master Hastings addressed the same argument in *Muchnick v. Secretary of HHS*, No. 97-89V, 1998 WL _____ (Fed. Cl. Spec. Mstr. July 15, 1998)(to be published), *aff'd*, ___ Fed. Cl. ___, 1998 WL 842768 (Nov. 18, 1998), and subscribed to respondent's position. In rejecting the Muchnick's claim that "respondent is prohibited from advancing JRA as a 'factor unrelated' allegedly causing Jessica's arthritis, pursuant to § 300aa-13(a)(1)(B)," the special master noted that the initial inquiry to be made is whether petitioners demonstrated a Table injury. *Muchnick* at 6.[27] In the analysis of that initial issue, the petitioners were bound by *the statutory language* which lists JRA as a disqualifying condition. The special master stated, "because Jessica has JRA, she does *not have a Table injury* in the first place." *Id.* at 7. Respondent's advancement of a JRA

diagnosis or cause was not presented in a "factor unrelated" context, as that discussion never arises due to the disqualifying language of the Vaccine Act. *Id.* The special master further noted "there is nothing in the statutory scheme to indicate that a condition of unknown cause, such as JRA, may not be used as a disqualifying criterion in the definition of a Table Injury itself." *Id.* I concur with Special Master Hastings' analysis and conclusion in *Muchnick*, and find petitioners' legal arguments in this case unpersuasive. Special Master Hastings' analysis logically examines express statutory language which prevents a petitioner from alleging a Table injury of chronic arthritis based on a diagnosis of JRA. In my view, the provision at issue operates as an exclusionary provision which governs the *initial determination* of whether a Table injury occurred.[(28)] Thus, the primary issue in this case is whether Kalynn's injury qualifies as a chronic arthritis Table injury under the Act. A finding that Kalynn's condition is juvenile rheumatoid arthritis requires, pursuant to the statutory scheme, a dismissal of petitioners' Table claim for failure to demonstrate an injury of chronic arthritis.

(2) Did Kalynn suffer from juvenile rheumatoid arthritis or non-JRA chronic arthritis?

As an initial matter, certain factual findings must be made before I can address the medical experts' opinions as they relate to Kalynn's alleged Table injury. Specifically, Christine Haynes' testimony regarding her daughter's condition in the days and weeks following the MMR vaccination provides both additional information and conflicts with the descriptions recorded in the medical records and her own affidavits. Therefore, I must factually determine the date of onset of Kalynn's arthritic symptoms. This is important because Dr. McCurdy testified that a vaccine-related arthritic condition would not have its onset earlier than two weeks following an MMR vaccination.

It should be noted that a special master may not find in favor of a petitioner based on the claims of petitioner alone, unsubstantiated by medical records or medical opinion. § 13(a)(1). However, the Act recognizes that medical records are not always accurate. § 13(b)(2). In cases where medical records are devoid of any mention of onset or contain a date or dates of onset that are inconsistent with petitioners' allegations, it has been held that the fact finder must closely scrutinize such testimony and, to meet their burden, petitioners must present thoroughly credible and persuasive testimony and/or documentary evidence to explain omissions or errors in the medical records. As the Federal Circuit noted in *Cucuras v. Secretary of HHS*, "oral testimony in conflict with contemporaneous documentary evidence deserves little weight." *Cucuras v. Secretary of HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993), *citing United States v. United States Gypsum Co.*, 333 U.S. 364 (1947). The Federal Circuit further stated:

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Id. at 1528.

In determining how to weigh oral testimony against conflicting medical record evidence, the Claims Court has stated that "written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later." *Reusser v. Secretary of HHS*, 28 Fed. Cl. 516, 523 (1993) (quoting *Murphy v. Secretary of HHS*, 23 Cl. Ct. 726, 733 (1992), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied*, 113 S. Ct. 463 (1992)). However, as Special Master Golkiewicz noted in *Stevens v. Secretary of HHS*, No. 90-221V, 1990 WL 608693 (Fed. Cl. Spec. Mstr. Dec. 21, 1990), "discrepancies between the testimony and records or gaps in the medical records are not in and of themselves decisive; clear, cogent and consistent testimony can overcome such missing or contradictory medical records." *Stevens v. Secretary of HHS*, No. 90-221V, 1990 WL 608693 (Fed. Cl. Spec. Mstr. Dec. 21, 1990).

More importantly, the conclusions of an expert are only as sound as their factual predicate. *Davis v. Secretary of HHS*, 20 Cl. Ct. 168, 173 (1990); *Loesch v. United States*, 645 F.2d 905, 915 (1981), *citing State of Washington v. United States*, 214 F.2d 33, 43 (9th Cir.), *cert. denied*, 348 U.S. 862 (1954); *Fehrs v. United States*, 620 F.2d 255, 265 (1980). I must thus carefully examine and weigh Mrs. Haynes' testimony before taking into account the experts' opinions.

Reviewing Mrs. Haynes' affidavits and testimony in conjunction with the medical records, I find that the medical records provide the most reliable picture of Kalynn's condition following her vaccination. Admittedly, some of the medical records are conflicting and vague regarding the onset or severity of the symptoms.(29) However, the medical records also consistently support that Kalynn's symptoms began within one to two days following her vaccination, *continued, and ultimately progressively worsened* in the weeks following until her August 1, 1994, hospitalization.(30) The records fail to demonstrate any "symptom-free" or asymptomatic period between a local reaction and the onset of an arthritic condition. Moreover, Dr. McCurdy's own notes reflect the continuous and progressive nature of Kalynn's symptoms. Tr. Ex. at 20. When the medical records are viewed in light of Mrs. Haynes' conflicting and deficient affidavit statements and testimony, their consistency and contemporaneous nature make them most persuasive to me in determining the facts of this case.(31)

Based on all of the evidence and having assessed the credibility of the witnesses, it seems more likely than not that by June 30 or July 1, 1994, Kalynn exhibited a refusal to walk (decreased ambulation), limping, stiffness and tenderness in the left thigh and buttock muscles (without redness or bruising), fussiness when standing, decreased sleeping, increased irritability (intermittent crying and fussing), and possible left hip pain and intermittent fevers. S*ee, supra, at footnote 29.* In the three weeks following the shot, Kalynn symptoms continued with limping (noted in one record to be mild), decreased ambulation, decreased sleeping, increased irritability, left hip pain with movement (*e.g.*, during diaper changes) and possible intermittent fevers. By July 18, 1994, Kalynn's limp became more dramatic and her left hip pain more significant, especially when being assisted from her crib and having her diaper changed. This worsening prompted a visit to her physician. Her symptoms continued to exacerbate until, in the days before her hospitalization, Kalynn exhibited greater difficulty walking and standing (*i.e.*, inability to bear weight, limping), leg stiffness, severe pain, decreased sleeping, increased irritability characterized by crying and screaming, and intermittent fevers.

Again, the primary issue in this case is whether Kalynn's injury qualifies as a chronic arthritis Table injury under the Act. A finding that Kalynn's condition is juvenile rheumatoid arthritis requires, pursuant to the statutory scheme, a dismissal of petitioners' Table injury claim. Conversely, a determination that Kalynn's condition *is not JRA* affords petitioners the presumption required to prevail on the Table injury claim, since it is not disputed that Kalynn developed chronic arthritis within 42 days of the vaccination which persisted for more than six months.

Juvenile Rheumatoid Arthritis: Both experts testified that criteria established by the American College of Rheumatology assists in the diagnosis of JRA. Tr. at 15, 24, 91. A patient's arthritis may be classified as JRA if (1) the individual is less than age 16 at the onset, (2) the arthritis has persisted 6 weeks or longer, and (3) other forms of juvenile arthritis have been excluded.(32) *Id.* at 15-18, 92; P. Ex. 36. In addition, the patient's arthritis should be classified as pauciarticular, polyarticular, or systemic in the first 6 months of the illness. Tr. at 27, 158; P. Ex. 36. Kalynn clearly meets the first and second requirements, and was diagnosed with pauciarticular JRA in the first 6 months of her illness. However, at dispute is whether other forms of juvenile arthritis have been excluded in Kalynn's case. Petitioners argue Kalynn's illness satisfies a Table injury claim of chronic arthritis which is related to the rubella vaccine; respondent disagrees and argues Kalynn's disease meets all requirements of JRA's diagnostic criteria. A thorough

review of the evidence in this case reveals petitioners' Table injury claim of chronic arthritis is significantly hampered by Dr. McCurdy's testimony and medical records and Dr. Lipnick's persuasive testimony, which together support a JRA diagnosis in this case.

First, Dr. McCurdy testified Kalynn's presentation meets a strict interpretation of the JRA criteria and that her current course and treatment is consistent with polyarticular JRA patients.(33) P. Ex. 31b at 1-2; Tr. at 14, 15, 35, 170, 172, 178.

Second, she diagnosed JRA (including pauciarticular and polyarticular) consistently nearly every month from September 1994 through February 1996 and July 1996 through September 1996, and expressly rejected the rubella vaccine's role. P. Ex. 6 at 141, 147-153; P. Ex. 38 at 435, 477, 482, 485, 488, 490, 508, 511, 515, 516, 518, 530, 533, 535; Tr. at 29.

Third, Dr. McCurdy has previously articulated her reasons for rejecting the vaccine and diagnosing JRA. For instance, in her September 14, 1994, letter to Dr. Corsino, Dr. McCurdy states she relied on the persistence of Kalynn's joint pain and swelling and a positive ANA of 1:320 to find a pauciarticular type of juvenile rheumatoid arthritis. P. Ex. 5 at 126-127. Although Dr. McCurdy noted, "this could have been triggered by the rubella vaccination," she also stated, "I think that this has persisted for too long to be strictly a post rubella vaccination synovitis." *Id.* at 127. Dr. McCurdy wrote she "therefore discussed with the parents a pauci-articular juvenile rheumatoid arthritis." *Id.*

Fourth, Dr. McCurdy's opinion that Kalynn presented atypically is without foundation. Her opinion relies partly on the symptomatic picture in existence approximately 20 days after the vaccination, on or about July 18, 1994. According to Dr. McCurdy, this is the date of onset for Kalynn's arthritis which represents a condition distinct and separate from the local reaction. Based on the medical records, which I believe most consistently and reliably document Kalynn's progress following her MMR immunization, I find it more likely than not that Kalynn's symptoms began one to two days following her vaccination and continued to progress throughout the weeks following, ultimately resulting in her hospitalization. In my view, Dr. McCurdy's opinion that Kalynn's symptoms 20 days post-vaccination were separate from those initially experienced in the days immediately following the inoculation, is simply without factual foundation.(34) In addition and notwithstanding the lack of factual foundation, Dr. McCurdy made several concessions which weaken her opinion. For instance, she conceded Kalynn did *not* develop spinal arthritis and exhibited good lumbar flexibility and hip range of motion. Tr. at 36, 37, 38, 161. She further admitted Kalynn's bone scan was in fact normal, as were the child's MRI and Gallium scan, and that an antalgic gait could result *alternatively* from hip problems. *Id.* at 157, 160; P. Ex. 31 at 2; *see also* P. Ex. 14 at 226.(35) This places in question Dr. McCurdy's reliance on Kalynn's alleged severe back pain to exclude a diagnosis of JRA. Dr. McCurdy also accepted at the hearing that pauciarticular patients exhibit asymmetrical joint symptoms and some JRA patients suffer dry synovitis later in their course. Tr. at 38, 150-151. Furthermore, the medical records fail to bolster her opinion. For instance, the contemporaneous records lack specific reference to an atypical JRA presentation. Admittedly, Dr. Lang's August 25, 1994, progress notes referenced an "unusual polyarthritis" and Dr. McCurdy's September and October 1994 letters cited a "complex" course. P. Ex. 7 at 156; P. Ex. 5 at 126, 128. In addition, Dr. McCurdy's October 5, 1994, progress notes stated that "[i]n view of previously [increased] HVA on urine & *unusual presentation* [w]ill do work up." P. Ex. 38 at 449 (Emphasis supplied). Nevertheless, Dr. McCurdy continued to diagnose Kalynn with JRA.(36) Neither the contemporaneous records, nor Mrs. Haynes' testimony, described back pain at the onset of Kalynn's symptoms on June 30 or July 1, or pain which moved from her muscles to her joints on or about July 18, 1994.(37) *See also* Tr. at 161. Furthermore, the medical records place the onset of Kalynn's rash and fever on August 4, 1994, not within 20 days of her vaccination, and Dr. Lang *specifically* related Kalynn's fever, rash, and pleocytosis to an acquired viral infection even though he considered Kalynn's arthritis possibly post-vaccinal.(38) Tr. Ex. at 18. In sum, I

am simply unconvinced that Kalynn's presentation was atypical, and, it would seem Dr. McCurdy concurred with this in her October 17, 1994, letter to Dr. Streng which states, "I think Kalynn *fairly clearly falls within the range of a polyarticular juvenile rheumatoid arthritis*." P. Ex. 5 at 128-129 (Emphasis supplied).

Lastly, Dr. Lipnick provided cogent and persuasive testimony to rebut Dr. McCurdy's testimony. Dr. Lipnick bases his overall testimony on the assumption, as gleaned from the medical records, that Kalynn's symptoms began within 24 to 48 hours following her vaccination and progressed thereafter. Second, Dr. Lipnick's testimony is bolstered by those instances in which Dr. McCurdy retracted her earlier testimony and contradicted her own records, and then agreed with his opinions in certain key respects. For instance, both agree Kalynn's presentation meets the JRA criteria and that Kalynn's positive ANA screen, swelling, and morning stiffness is evidence supporting pauciarticular JRA.[(39)] R. Ex. A at 2; Tr. at 77, 81, 100, 143. In addition, Dr. McCurdy ultimately accepted, as Dr. Lipnick opines, that Kalynn's asymmetrical joint involvement is consistent with pauciarticular JRA and that Kalynn did not develop spinal arthritis. Tr. at 37-38, 85-86, 109, 150-151, 180. Third, Dr. Lipnick also testified in accordance with the medical records. For instance, while he could not explain Kalynn's lumbar pain, he noted consistent with the records and contrary to Dr. McCurdy's initial testimony that the bone scan petitioners' expert relied on returned normal. *Id.* at 142. Dr. Lipnick also testified, as the records support, that Kalynn's rash and fever were unrelated to her arthritic picture. *Id.* at 145.

In short, JRA has been Dr. McCurdy's working diagnosis for years. What complicates the analysis is her current inability to accept or reject juvenile rheumatoid arthritis in this case. Clearly, Dr. McCurdy's direct acceptance of the diagnosis ends petitioners' Table injury claim. Conversely, rejection of the diagnosis raises credibility questions; after all, her own records are replete with the JRA diagnosis. Thus, Dr. McCurdy advocates petitioners' claims by theorizing that because JRA's etiology is unknown, she cannot rule it out. *Id.* at 163-164, 165. Her opinion suggests that arthritis caused by the rubella vaccination may also be diagnosed as JRA. This convoluted opinion both assists and damages petitioners' case. It enables Dr. McCurdy to make statements which seemingly conflict, but by her theory do not. It allows Dr. McCurdy to have the benefits of both diagnoses. For instance, it permits Dr. McCurdy's opinion that Kalynn's condition is post-vaccinal JRA, in support of petitioners' causation-in-fact case. It also enables Dr. McCurdy's testimony that she *never changed* her opinion from JRA to post-rubella chronic arthritis because no one knows JRA's etiology, implying the diagnoses are possibly intertwined. *Id.* at 163-164. However, Dr. McCurdy's "semantics" quandary, as she explains it, fails for two reasons thereby damaging her credibility.

First and despite her contrary testimony, it appears Dr. McCurdy herself viewed post-vaccinal arthritis and JRA as *two separate and distinct illnesses*. Her records reveal, and Dr. McCurdy admitted, that the rubella vaccine was *considered but rejected* as the cause of Kalynn's condition; JRA was *then diagnosed*. [(40)] In addition, her records demonstrate a clear *change in opinion* at various times over Kalynn's course. For example, on August 22, 1994, Dr. McCurdy listed the diagnosis as "Post rubella shot/arthritis." P. Ex. 6 at 138; P. Ex. 38 at 427. However, for months thereafter she diagnosed JRA. On April 23, 1996, one month after her first expert report filed in this matter, Dr. McCurdy listed Kalynn's diagnosis as "JRA/post vaccination reaction," but crossed out "JRA"; her impression is then simply recorded as "Arthritis." P. Ex. 38 at 520; s*ee also Id.* at 524 (May 15, 1996). From July through September 1996, Dr. McCurdy's diagnosis reverted to pauciarticular JRA, although Dr. McCurdy also made references such as "Pauci JRA--Chronic arth[ritis] after Rubella Vac[cination]" and "Pauci JRA-like post vaccination arthritis." *Id.* at 530, 535. From October 1996 through September 1997, Dr. McCurdy diagnosed arthritis and post-vaccinal arthritis.[(41)] *Id.* at 538, 541, 543, 544, 545, 550, 551, 554, 556, 561.[(42)] These chart notations, and particularly those parts edited by crossing out JRA, clearly show a change in diagnosis starting in April 1996. While they promote Dr. McCurdy's opinion that Kalynn's condition is related to the vaccination, they also seriously diminish her testimony that she can neither accept nor reject juvenile

rheumatoid arthritis in this case. Second, by logic and Dr. McCurdy's own opinion, arthritis caused by the rubella vaccination cannot be termed JRA, because then the etiology of the condition is known.[(43)] This logical analysis is endorsed by Dr. Lipnick, who concurs that, by definition, arthritis induced by the rubella vaccine is not JRA. Tr. at 93-94. Again, two separate illnesses are at issue here.

While Dr. McCurdy *is* entitled to change her opinion, her convoluted testimony obscures her ultimate position. She equivocates between atypical JRA and rubella-induced arthritis. The evidence, on its face, endorses a finding of juvenile rheumatoid arthritis. Dr. McCurdy's medical records reference JRA. She testified Kalynn's presentation meets the JRA criteria and that she cannot reject JRA in this case. And her final argument, that Kalynn presented with *atypical* JRA is weak. But Dr. McCurdy also posits an alternative finding that the vaccine caused or triggered Kalynn's arthritis.[(44)] Because I agree with Dr. Lipnick that chronic arthritis caused by the vaccine cannot be JRA by definition, I am also obligated to address Dr. McCurdy's opinion in this respect as well.[(45)]

Rubella-associated chronic arthritis (non-JRA): Petitioners' claim of rubella-associated arthritis is most damaged by Dr. McCurdy's concession that Kalynn's symptoms do not fit a post-rubella picture if they began immediately following the vaccination and progressed thereafter.[(46)] Tr. at 77, 171, 172, 178-179. The experts agreed 24 to 48 hours is insufficient incubation time for a rubella-related reaction to commence. *Id.* at 172, 178-179. These concessions alone provide sufficient reason to dispose of petitioners' claim, since I have determined that Kalynn's symptoms began within 24 to 48 hours after the vaccination and progressed thereafter. However, Dr. McCurdy's opinion is weak for other reasons.

First, Dr. McCurdy unpersuasively relies on her initial contacts with the infectious disease specialists in 1994 to posit a post-vaccinal picture now. *Id.* at 151, 153. She claims the MMR was considered from the start and that Kalynn's physicians related her rash and fever to the vaccination. *Id.* at 170. But this reliance on the physicians' early discussions falters when pitted against the medical records and Dr. McCurdy's own testimony. Admittedly, Kalynn's discharge diagnosis reported a "post-immunization rheumatologic condition." P. Ex. 4 at 121-122. But subsequent records show a refinement and change in that diagnosis. For instance, Kalynn's rash and fever were attributed to a hospital-acquired aseptic meningitis, not to her vaccination. Dr. McCurdy documented this in her own records and agreed that Kalynn's rash and fever could be consistent with a viral meningitis acquired at the hospital or to another cause. P. Ex. 5 at 128; P. Ex. 6 at 137; P. Ex. 38 at 426; Tr. at 170.[(47)] Dr. McCurdy also agreed that a rubella-related rash 35 days after the inoculation is uncommon. Tr. at 153-155, 170-171. In addition, Kalynn's diagnosis was listed as JRA in numerous subsequent reports by Dr. McCurdy and her colleagues, and this diagnosis was relied upon for treatment, therapy evaluations (physical and occupational), and various radiological tests. Not only were bases given for terming Kalynn's condition JRA, but it was noted that Kalynn's rubella virus isolation tests returned with negative results.[(48)] P. Ex. 5 at 126; *see also* the rubella titer results at P. Ex. 8 at 163, 164, 166.

Second, Dr. McCurdy's opinion is unsupported by the literature. Dr. McCurdy testified she re-considered the vaccine's role subsequent to her review of relevant literature. Tr. at 29-33. But she also acknowledged that the literature she submitted does not establish a causal link between chronic arthritis in children and the rubella vaccination; instead, researchers continue to study whether there exists such an association.[(49)] *Id.* at 45, 167-169. I have found no support in the literature establishing a link between the rubella vaccination and chronic arthritis in children.[(50)]

Third, Dr. McCurdy's opinion is weakened by its equivocal nature about the rubella vaccine's role in chronic arthritis cases and Kalynn's case particularly. For instance, Dr. McCurdy's first expert report, dated March 1, 1996, stated "*[i]t is likely there is an association* of the arthritis with the vaccination." P.

Ex. 31 at 4 (Emphasis supplied). In her first supplemental expert report, prepared three months later, she opined "that the rubella vaccination *may initiate a chronic arthritis in a genetically susceptible individual. Therefore, it is my opinion based on reasonable medical probability that Kalynn suffers from chronic arthritis from her MMR vaccination*." P. Ex. 31a at 2 (Emphasis supplied). In her second supplemental expert report, given October 30, 1996, Dr. McCurdy wrote: "[the rubella vaccination] *certainly may have played a role* in this chronic arthritis from which Kalynn suffers." P. Ex. 31b at 2 (Emphasis supplied). Dr. McCurdy was also reluctant at the hearing to link Kalynn's problems to her MMR vaccine based on reasonable medical probability. Tr. at 176-178. After much hedging, Dr. McCurdy agreed she holds her opinion, that "the triggering event was the rubella vaccination in this particular case of arthritis," to greater than a 51% level of certainty.[(51)] *Id*. at 176.

Dr. Lipnick's testimony on this issue is again cogent and persuasive. For instance, his testimony that Kalynn's joint symptoms began too early to be rubella-related is supported by the medical records, Dr. McCurdy's concessions, and the literature. Dr. Lipnick's testimony that Kalynn's rash developed much too late to be related to the MMR, and was instead related to aseptic meningitis or another viral infection, is similarly supported. Furthermore, Dr. Lipnick testified in accordance with the literature that the role of the vaccination in chronic arthritis in children is inconclusive at this time.

I am simply convinced that the evidence supports the JRA diagnosis in this case. Dr. McCurdy has provided no compelling reasons to ignore her own records and testimony, and I conclude that juvenile rheumatoid arthritis *(i.e.*, non-vaccine related arthritis) represents Dr. McCurdy's true contemporaneous medical judgment in this case. I am also persuaded by Dr. Lipnick's convincing testimony which is supported not only by the medical records, and the literature, but by Dr. McCurdy's own testimony as well in certain important instances. I also note the importance that credibility plays in this case given that Dr. McCurdy functions not only as Kalynn's treating physician, but as her expert witness as well. While this fact alone does not connote that I systematically dismiss Dr. McCurdy's opinions because of potential bias, I am struck by the convoluted nature of her opinions, which seemed to revert to a post-vaccinal diagnosis at about the time she rendered expert reports in this case for purposes of litigation.[(52)] In any event, and even putting this notion aside, I ultimately find Dr. Lipnick's testimony more credible on the issue of whether Kalynn suffers from JRA. His testimony was straightforward and unwavering, in contrast to Dr. McCurdy's, and was corroborated by and based upon the contemporaneous medical records, which I have found reliable. Therefore, by statute, petitioners' Table injury claim of chronic arthritis fails. Accordingly, petitioners' remaining theory of recovery is to demonstrate by a preponderance of evidence that the rubella vaccination caused-in-fact Kalynn's juvenile rheumatoid arthritis.

Causation-in-fact

In order to demonstrate entitlement to compensation in an off-Table case, a petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. §§11(c)(1)(C)(ii)(I) and (II); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-370 (1990), *aff'd without opinion*, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit in *Grant* summarized the legal criteria required to prove causation-in-fact under the Vaccine Act:

[A petitioner must] show a medical theory causally connecting the vaccination and the injury. Causation-in-fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F.2d at 1148 (citations omitted); *see also Strother*, 21 Cl. Ct. at 370.

Petitioner does not meet this affirmative obligation by merely showing a proximate temporal association between the vaccination and the injury. Rather, petitioner must explain *how* and *why* the injury occurred. *Strother*, 21 Cl. Ct. at 370; *see also Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983), *cert. denied*, 469 U.S. 817 (1984) ("inoculation is not the cause of every event that occurs within the ten day period [following it] . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation"). If petitioner places "singular reliance on the temporal relationship between the administration of the vaccine and the onset of symptoms," the claim must fail. *Thibaudeau v. Secretary of HHS*, 24 Cl. Ct. 400, 403 (1991). Nor may petitioner meet his burden by eliminating other potential causes of the injury. *Grant*, 956 F.2d at 1149-50. Petitioner's theory "must be supported by a sound and reliable medical or scientific explanation." *Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994). "[E]vidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation" for petitioners seeking to prove actual causation. H.R. Rep. No. 990908, 99th Cong. 2d Sess., pt. 1 at 15 (Sept. 26, 1986), *reprinted in* 1986 U.S. Code Cong. and Admin. News 8344, 8356. The general acceptance of a theory within the scientific community of a scientific theory can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. *Daubert v. Merrell Dow Pharmaceuticals, Inc*. 113 S. Ct. 2786, 2797 (1993).

Under the Table injury route, after petitioner has demonstrated the requirements of §13(a)(1)(A), the burden shifts to the respondent to prove the injury was caused by factors unrelated to the vaccination in question pursuant to § 13(a)(1)(B). *Matthews v. Secretary of HHS*, 18 Cl. Ct. 514, 518 (1989); *O'Connor v. Secretary of HHS*, 24 Cl. Ct. 428, 429-430, fn.2 (1991), *aff'd*, 975 F.2d 868. In an actual causation case such as this, however, the inquiry is "collapsed into a single determination: On the record as a whole, has petitioner proven, by a preponderance of the evidence, that her injury was in fact caused by the administration of a listed vaccine, rather than by some other superseding intervening cause?" *Johnson v. Secretary of HHS*, 33 Fed. Cl. 712, 722 (1995), *aff'd*, 99 F.3d 1160 (Fed. Cir. 1996). *See also, Bradley v. Secretary of HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993); *Munn v. Secretary of HHS*, 970 F.2d 863, 865 (Fed. Cir. 1992); *Wagner v. Secretary of HHS*, No. 90-2208V, 1997 WL 617035 (Fed. Cl. Spec. Mstr. Sept. 22, 1997)(dec. on remand). *But see Wagner v. Secretary of HHS*, 37 Fed. Cl. 134, 138 (1997) (once petitioner puts on her prima facie case, the burden shifts to respondent to prove a factor unrelated to the administration of the vaccine caused the injury); *O'Connor v. Secretary of HHS*, 24 Cl. Cl. 428, 429-430, fn.2 (1991), *aff'd*, 975 F.2d 868 (Fed. Cir. 1992); *McClendon v. Secretary of HHS*, 24 Cl. Ct. 329, 333 (1991), *aff'd*, 41 F.3d 1621 (1994).

In order to answer the single inquiry of whether, based on the record as a whole, the evidence preponderates in favor of a finding that Kalynn's JRA was caused by the rubella vaccination, one must pursue a two-step analysis: (1) *can* the MMR vaccine cause JRA? and (2) *did* the MMR inoculation in question in-fact cause Kalynn's JRA in this case? *See Guy v. Secretary of HHS*, No. 92-779V, 1995 WL 103348 (Fed. Cl. Spec. Mstr. Feb. 21, 1995); *Alberding v. Secretary of HHS*, No. 90-3177V, 1994 WL 110736 (Fed. Cl. Spec. Mstr. Mar. 18, 1994); *Housand v. Secretary of HHS*, No. 94-441V, 1996 WL 282882 (Fed. Cl. Spec. Mstr. May 13, 1996).

(1) C*an the MMR vaccine cause JRA?*

As noted above, a temporal relationship alone does not suffice to prove causation in an off-Table case. Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that "*Daubert* is useful in providing a framework for evaluating the reliability of scientific evidence." *Terran v. Secretary of HHS*, 41 Fed. Cl. 330, 336 (1998), *on appeal*, (citing *Leary v. Secretary of HHS*, No. 90-1456V, 1994 WL 43395, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 1994)). In *Daubert*, the Supreme Court noted that scientific knowledge "connotes more than subjective belief or unsupported speculation." *Daubert*, 113 S.Ct. at 2795. Rather, some application of the scientific method

must have been employed to validate the expert's opinion. *Id*. Factors relevant to that determination may include, but are not limited to:

whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), *on remand from* 113 S.Ct. 2786 (1993); *see also Daubert*, 113 S.Ct. at 2796-97.

When viewed in light of the factors listed above, I conclude the evidence provides no reasonable basis for concluding that the MMR vaccination can cause or trigger juvenile rheumatoid arthritis.(53) As already mentioned, both Dr. McCurdy and Dr. Lipnick testified that there is no substantial evidence causally linking the MMR vaccine with the onset of chronic arthritis or JRA in children. Dr. McCurdy also acknowledged the articles she submitted do not link the vaccine to chronic arthritis in children. Tr. at 45. My review of the literature confirms this finding. While the articles support an association between the rubella vaccine and arthritis, they fail to adequately address the role the vaccine plays in triggering or causing *JRA*.(54) For the most part, the literature concentrates on the vaccine's role in causing arthritis generally in children or expressly in adults. In fact, only Petitioners' Exhibit 28 focuses on JRA and there the authors note: "In the case of juvenile rheumatoid arthritis, the evidence for involvement of rubella virus has been much more tenuous." P. Ex. 28 at 1117 (Janet Kathleen Chantler, *et al., Persistent Rubella Virus Infection Associated with Chronic Arthritis in Children,* 313 The New england Journal of Medicine 1117 (1985)). The authors further conclude that the "[p]ersistence of rubella virus in lymphoreticular cells in 35 per cent of these cases of juvenile arthritis supports the view that the virus may be an etiologic agent in chronic human joint disease, but further work will be required to support this suggestion."(55) *Id.*; *see also* P. Ex. 29 at 2054 ("A potential relationship of rubella virus with juvenile RA (JRA) has been suggested, because virus has been recovered from peripheral blood and synovial fluid mononuclear cells from children with JRA.")(*Rubella Virus*, 2 Arthritis and Allied Conditions: A Textbook of Rheumatology 2054 (1993)). Thus, I find no *persuasive support* in the literature that the rubella virus causes or triggers JRA, nor does that theory appear to enjoy acceptance in the medical community. Instead, the research appears to be continuing in this arena of medicine.

(2) *Did the MMR inoculation in question in-fact cause Kalynn's JRA in this case?*

Because petitioners' claim fails on the first prong of the causation-in-fact analysis, the second inquiry need not be addressed. However, even if petitioners prevailed on prong one, they would be unable to demonstrate by a preponderance of the evidence that the MMR inoculation Kalynn received caused or was a substantial factor in bringing about her JRA.(56) This is because both experts testified that if Kalynn's symptoms began within 24 to 48 hours after her inoculation, as I have found to be the case, then her symptoms cannot be related to a rubella reaction. The journal articles support the experts' testimony and none of the articles substantiate that the onset of rubella-related symptoms can occur within one to two days following vaccination. P. Ex. 29 at 2053; P. Ex. 32 at 2268 (Leslie A. Mitchell, PhD, *et al., Chronic Rubella Vaccine-Associated Arthropathy*, 153 Archives of the Internal Medicine 2268 (1993)). Moreover, testing similar to that conducted in the articles filed did not take place in Kalynn's case, and in any event, the rubella virus was not isolated here. Thus, there is no physiologic evidence to support that Kalynn's arthritis is rubella-related. Although Kalynn may have suffered symptoms similar to those experienced by the study participants discussed in the various articles, the evidence simply does not preponderate in favor of a finding that Kalynn's rubella vaccine caused-in-fact her JRA.

Likewise, any cause-in-fact claims that the MMR can cause chronic arthritis (non-JRA) in children, and

did so here, are also rejected.[57] Again, the literature and expert testimony fail to demonstrate a consensus in the scientific community that there is substantial evidence causally linking the rubella vaccine with the onset of chronic arthritis in children.[58] While Petitioners' Exhibit 33a states that the "[m]easles, mumps, and rubella vaccine is associated with an increased risk of episodes of joint and limb symptoms, especially in girls and children under 5," the study fails to address the rubella vaccine's role in *chronic cases* of arthritis in children. P. Ex. 33a at 1075 (C.M. Benjamin, *et al. Joint and limb symptoms in children after immunisation with measles, mumps, and rubella vaccine*, 304 British Medical Journal 1075 (1992)). Instead, most of the participants experienced short-lived episodes which resolved spontaneously, with "little consequence." *Id.* at 1077. The second prong of the cause-in-fact inquiry would also fail for the same reasons above stated in the analysis of the causal relationship between the MMR vaccine and Kalynn's JRA.

VI.

FINDINGS OF FACT

1. As parents and legal representatives of the minor child, Kalynn, who received the vaccination, petitioners have the requisite capacity to bring this action. § 11(b)(1)(A).

2. Petitioners have not previously collected an award or settlement of a civil action in connection with any alleged injury sustained by Kalynn due to the administration of the MMR vaccine in question. § 11 (c)(1)(E); Petition at 3.

3. Kalynn was administered a vaccine listed in the Vaccine Injury Table.

§ 11(c)(1)(B)(i)(I); Petition at 2.

4. Said vaccine was administered in the United States, in Chino, California.

§ 11(c)(1)(B)(i)(I); Petition at 2.

5. There is not a preponderance of the evidence that Kalynn suffered chronic arthritis as defined by the Vaccine Injury Table.

6. There is not a preponderance of the evidence that the MMR vaccination administered to Kalynn on June 29, 1994, caused-in-fact her juvenile rheumatoid arthritis.

7. There is not a preponderance of the evidence that petitioners expended in excess of $1000 in unreimbursed medical expenses as a result of a vaccine-related injury.[59]

VII.

CONCLUSION

Based on the foregoing, the undersigned finds, after considering the entire record in this case, that petitioners are not entitled to compensation in this case under the Vaccine Act. In the absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

Elizabeth E. Wright

Special Master

1. The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C.A. §§ 300aa-1 through -34 (West 1991 & Supp. 1998)). References shall be to the relevant subsection of 42 U.S.C.A. § 300aa.

2. The evidence in the record consists primarily of exhibits submitted by petitioners as part of the petition and in preparation for trial ("P. Ex. ____"), respondent's exhibits filed in this matter ("R. Ex. ____"), plus evidence taken at the evidentiary hearings conducted September 23, 1997, and January 20, 1998 ("Tr. at ____"). Petitioners' medical records, for the most part, are numbered consecutively; however, they are also separated by exhibit. Therefore, citations to Kalynn's medical records will reference both the exhibit number and the consecutive page number, *e.g.*, "P. Ex. 38 at 422." The medical records submitted during the September 23, 1997, hearing, by facsimile, which consist of twenty-six pages of records from Kalynn's hospitalization at the Children's Hospital of Orange County, will be referenced as "Tr. Ex. at ___." These transcript exhibits have been filed by leave of the special master on February 25, 1999. The transcripts from the two hearings are also numbered consecutively; therefore, reference to a specific hearing will be provided only when appropriate.

3. There are only a few contemporaneous medical records which outline Kalynn's symptoms as they occurred in the days and weeks immediately following her vaccination. Instead, most of Kalynn's prior medical history is provided by the physicians documenting that history upon Kalynn's hospitalization in August 1994.

4. The date of this record is unascertainable from the undersigned's copy. The date is obscured by a "hole-punch" but falls on or before the July 22, 1994, entry.

5. Dr. Ismail noted the history was provided by Kalynn's parents. P. Ex. 18 at 366.

6. *See also* Dr. Jeffrey Levin's Consultant's Report on Kalynn's August 5, 1994, evaluation. P. Ex. 5 at 135-136. Dr. Levin provided a similar history: "Later [after the MMR vaccination] there was stiffness and swelling in the left thigh muscle and the patient was limping and had tenderness that got progressively worse with pain, with brushing of the thigh and pain in the left groin region." *Id.* at 135. Dr. Levin diagnosed Kalynn with "Subacute case of weakness after immunizations. Concerns would be a resolving transverse myelitis, a resolving acute infectious polyneuropathy or lastly a secondary infection such as Lyme disease or other chronic infection causing neuropathy." *Id.* at 136.

7. Kalynn's chest views and whole body bone scan, conducted in October 1994, were also normal. P. Ex. 9 at 188-189, 192; P. Ex. 37; P. Ex. 38 at 453, 567.

8. JRA is divided into three types: pauciarticular, polyarticular, and systemic. Pauciarticular JRA occurs when 4 or less joints are involved, characteristically in an asymmetrical pattern. Polyarticular JRA involves more than four joints and patients present with symmetrical involvement. Systemic JRA patients usually present with high spiking fevers, rashes, high white blood cell counts, and possible inflammation of the lining of the heart, lungs, and/or abdomen; joint involvement may or may not occur in the first six months. The particular JRA diagnosis is based on an assessment of the patient's first six months of illness.

Tr. at 17, 84-86.

9. *See, e.g.*, P. Ex. 38 at 520 (April 23, 1996), 524 (May 15, 1996), 530 (July 9, 1996), 535 (September 24, 1996), 538 (October 29, 1996), 541 (December 16, 1996), 543 (January 28, 1997), 544 (March 11, 1997), 545 (April 16, 1997), 550 (May 6, 1997), 551 (May 28, 1997), 556 (July 29, 1997); P. Ex. 38 at 497 (June 2, 1995), 521 (April 25, 1996), 532 (July 10, 1996), 548 (April 16, 1997), 552 (May 28, 1997), 555 (June 25, 1997). Where Dr. McCurdy's Rheumatology Visit reports are not dated via hand-written means, I have cited the printed date listed to the right of Kalynn's Case ID number which is located in the top left hand corner of each document.

10. Dr. McCurdy is board certified in pediatrics. Tr. at 8. As the Director of Rheumatology at Children's Hospital of Orange County, Dr. McCurdy focuses her practice strictly on rheumatology issues such as lupus and juvenile rheumatoid arthritis. *Id.* She has concentrated on rheumatoid problems in pediatric patients since 1986, and has seen approximately 1000 children with JRA over the course of her practice. *Id.* at 9, 11-12. Dr. McCurdy is the principal treating physician for Kalynn's rheumatoid problems; she has seen Kalynn approximately once a month since August 1994. *Id.* at 9-10. In addition to the medical records filed which reference Dr. McCurdy as Kalynn's treating physician, Dr. McCurdy also provided three expert reports, which have been filed as Petitioners' Exhibits 31 (dated March 1, 1996), 31a (dated June 5, 1996), and 31b (dated October 30, 1996).

11. Dr. McCurdy also testified that reactive arthritis typically resolves spontaneously. Tr. at 158.

12. In opining that Kalynn presented atypically, Dr. McCurdy relies on the symptoms she believes Kalynn exhibited on or about July 18, 1994. Dr. McCurdy posits that Kalynn's symptoms at that time were atypical to support both her positions, *i.e.*, that the onset of Kalynn's symptoms was more indicative of a post-vaccinal scenario and, alternatively, that Kalynn's initial symptoms were not typical for JRA. She testified that she sees a few atypical JRA cases every year, but those patients are diagnosed with post-reactive synovitis or other illnesses (*e.g.*, SEA Syndrome), and are not termed JRA. Tr. at 26. To further confuse the discussion, Dr. McCurdy testified that patients may be initially diagnosed with JRA, but as the course progresses atypically, another diagnosis may be warranted. *Id.* Although Dr. McCurdy stated that Kalynn's presentation on or about July 18, 1994, *and her subsequent course* were atypical, she has also testified that as Kalynn's condition became chronic, the child's course followed that expected in JRA patients. *Id.* at 12, 16, 22, 27, 28, 34-35, 39, 40, 115, 162, 170, 172.

13. Dorland's Illustrated Medical Dictionary defines **lordotic** as "pertaining to or characterized by lordosis." **Lordosis** is defined as "the anterior concavity in the curvature of the lumbar and cervical spine as viewed from the side. The term is used to refer to abnormally increased curvature (hollow back, saddle back, swayback) and to the normal curvature (normal lordosis)." Dorland's illustrated medical dictionary 954 (27th Ed. 1988)(hereinafter "Dorland's") .

14. Dorland's Illustrated Medical Dictionary defines **antalgic** as "1. counteracting or avoiding pain, as a posture or gait assumed so as to lessen pain. 2. analgesic." Dorland's at 95.

15. Dr. McCurdy also pointed to her August exam which revealed, she believes, clear back pain evidenced by marked lumbar lordosis, pain on palpation in the lower lumbar region, and antalgic gait. Tr. at 55-56.

16. Dr. McCurdy also testified Kalynn presented atypically for *systemic* JRA, although the presence of a fever and rash would suggest a systemic JRA diagnosis rather than pauciarticular JRA. Tr. at 12, 13, 112, 113-115, 150. Nevertheless, Dr. McCurdy found that Kalynn's fever, rash, and multiple joint involvement presented differently than expected in systemic cases and, therefore, never entertained the diagnosis. *Id.*

17. Dr. McCurdy also testified, "[F]rom my standpoint, no, she does not have JRA, but I think what we have to say, and this is where you are going to get disagreement from any rheumatologist, is I don't think any of us can totally agree on what JRA is. From my standpoint, from the other cases of JRA I've seen, her course is atypical, and I would prefer to call her a chronic arthropathy." Tr. at 40.

18. Dr. McCurdy testified early in the first hearing that she did not recall labeling Kalynn's condition JRA. Tr. at 27. Given that this diagnosis was recorded repeatedly by Dr. McCurdy between September 1994 and September 1996, and that presumably Dr. McCurdy reviewed Kalynn's file prior to her testimony, this testimony struck me as particularly odd.

19. Dr. Lipnick is board certified in pediatrics and pediatric rheumatology. Tr. at 79. He privately practices pediatric rheumatology where 98% of his patients are children with JRA. *Id.* at 78-79. He has seen 1000 to 1500 JRA patients, but has never had a patient develop arthritis relating to the MMR vaccine. *Id.* at 115-116, 148-149.

20. Dr. Lipnick considered Kalynn's presentation so typical, he believed she would make an appropriate teaching case. Tr. at 181.

21. Dr. Lipnick testified Kalynn's initial history of morning stiffness was "very suggestive of JRA." Tr. at 81, 84, 100-101, 144. He contrasted this symptom with that experienced by chronic arthritis (non-JRA) patients, who typically suffer stiffness and pain throughout the entire day, rather than just the morning hours. *Id.* at 144.

22. Petitioners must prove their case by a preponderance of the evidence, which requires that the trier of fact "believe that the existence of a fact is more probable than its nonexistence before [the special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." *In re Winship*, 397 U.S. 358, 372-373 (1970) (Harlan, J., concurring) *quoting* F. James, Civil Procedure 250-251 (1965). Mere conjecture or speculation will not establish a probability. *Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (Cl. Ct. 1984).

23. § 14(a). A petitioner may also establish a rebuttable presumption by demonstrating that a Table injury has been significantly aggravated, within the Table time period, by a listed vaccine. § 11(c)(1)(C)(i).

24. 42 C.F.R. § 100.3(a)(II)(b)(A).

25. § 13(a)(1)(B). Other prerequisites to compensation include: (1) that the injured person suffered the residual effects of a vaccine-related injury for more than six months after the administration of the vaccine. § 11(c)(1)(D)(i); (2) that the petitioner incurred in excess of $1000 in unreimbursable vaccine-related expenses. § 11(c)(1)(D)(i); (3) that the vaccine was administered in the United States. § 11(c)(1)(B)(i)(I); (4) that the petitioner did not previously collect a judgment or settlement in a prior civil action. § 11(c)(1)(E); and (5) that the action be brought by the injured person's legal representative. § 11(b)(1)(A).

26. To be entitled to compensation under the Act, a special master must find that a petitioner demonstrated, by a preponderance of evidence, not only the matters required in § 11(c)(1), but also that petitioner's injury is not "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(A) and (B). A "factor unrelated" "does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." § 13(a)(2)(A).

27. At this time, it is anticipated that the special master's decision in *Muchnick* will soon be published on Westlaw and Lexis/Nexis. Until then, however, page citations will be to the original decision, not to the

pages on Westlaw of Lexis/Nexis.

28. Petitioners' counsel cites the Federal Circuit's decision in *Knudsen v. Secretary of HHS*, 35 F.3d 543 (Fed. Cir. 1994), for the proposition that "compliance with a Table-defined time- frame, where satisfaction of the sequela requirement is present, establishes the claim in question as a 'Table Injury'." P. Brief at 5 (footnotes omitted). Counsel thus argues that because Kalynn suffered chronic arthritis within the Table time period and for six months thereafter, the burden then shifts to respondent to demonstrate that a factor unrelated to the administration of the vaccination caused Kalynn's chronic arthritis. *Id.* at 4-5. Counsel essentially claims that § 100.3(b)(6)(ii) goes not to petitioners' initial burden to show whether a Table injury occurred, but to respondent's factor unrelated burden of proof. Petitioners' counsel then concludes respondent is barred from asserting JRA as a factor unrelated, given its unknown etiology. *Id.* at 5-7. Although I reject petitioners' arguments, even were I to agree with petitioners' position, that § 100.3(b)(6)(ii) governs the factor unrelated issue, the Federal Circuit held in *Knudsen* that "a 'viral' infection can be an alternative causation, even though the viral infection is not in the particular case specifically identified by type or name. Thus, the government may defeat a petitioner's claim with a theory of viral infection so long as it proves that there was in fact a viral infection, and that the viral infection 'in the particular case [was] . . . principally responsible for causing the petitioner's illness, disability, injury, condition, or death.'" *Knudsen* at 549. While *Knudsen* specifically dealt with the provision promulgated by Congress which excludes from the determination of an encephalopathy one caused by "infection, toxins, trauma, or metabolic disturbances," Congress *similarly* specifically excluded JRA from the definition of a chronic arthritis injury. § 14(b)(3)(B). Using parallel logic and assuming *arguendo* that respondent's JRA allegation should be viewed as a factor unrelated defense, the fact that JRA's etiology is unknown should not prevent respondent from successfully demonstrating that JRA caused Kalynn's arthritis, so long as respondent proved Kalynn had JRA and JRA was principally responsible for causing her illness.

29. The medical records conflict in four circumstances but not to the detriment of my conclusions. First, Dr. Streng reports Kalynn's limping began three to four weeks prior to her appointment; the date of the visit is unclear, but Dr. Streng examined Kalynn on or before July 22, 1994. However, in the same notation, Dr. Streng implies the limping began at least one week *after* the vaccination. In greater contrast, a Children's Hospital record suggests the limping began *before* the vaccination. When pitted against the other records in this case, two of which provide specific dates, Kalynn's limping clearly began June 30 or July 1. Second, several records report the onset of left hip pain one week after the vaccination, while Dr. Lin's July 18 appointment notes reveal a three week history of left hip pain, suggesting Kalynn's pain began immediately following her vaccination. The onset of Kalynn's left hip discomfort remains unclear; this is not surprising given Kalynn's inability at the time, because of her age, to verbalize her pain. In any event, Kalynn suffered left hip pain within one week following her vaccination, which persisted until her hospitalization. Third, it is unclear whether Kalynn suffered swelling in the one to two days following the vaccination. Dr. Ismail's neurology evaluation reveals there was no swelling; however, Dr. Levin cites swelling, but does not provide an onset date. The records are simply unclear on this. Fourth, the records conflict regarding whether Kalynn suffered fevers in the weeks following her vaccination. Mrs. Haynes testified Kalynn did not have a fever on June 30, 1994. At most, based on the medical records, I conclude it is possible Kalynn suffered intermittent fevers in the weeks following her inoculation, and likely experienced definite fevers in the days immediately prior to her hospitalization.

30. The contemporaneous medical records consistently reflect the progressive nature of Kalynn's illness. Within one to two days following her vaccination, Kalynn suffered limping, crying, fussiness, stiffness and tenderness in the left hip. P. Ex. 4 at 48; P. Ex. 17 at 346; P. Ex. 18 at 366; Tr. Ex. at 1, 3, 5. Her symptoms continued and progressed throughout the following weeks, accompanied by persistent left hip pain and mild limping. P. Ex. 17 at 346; P. Ex. 18 at 366; Tr. Ex. at 5. By July 18, Kalynn experienced significant pain, obvious limping, and refused to permit movement of her left hip. P. Ex. 18 at 367. By

July 28, 1994, Kalynn experienced severe pain and refused to walk or stand. P. Ex. 14 at 212; P. Ex. 17 at 346, 347; P. Ex. 18 at 367; Tr. Ex. at 5, 20.

31. Moreover, I am persuaded by Dr. Lipnick's testimony that the symptoms which manifested within one to two days following Kalynn's vaccination represented an arthritic condition. Dr. Lipnick relies on Kalynn's limping and unwillingness to walk on July 1, 1994, as evidence of joint pain. Tr. at 82-83. He further believes the intermittent nature of her signs and symptoms over the subsequent weeks was very suggestive of JRA. *Id.* at 84, 180. In addition, Dr. McCurdy testified that she would, nevertheless, view Kalynn's condition as arthritic, even if Kalynn's symptoms were found to be progressive. *Id* at 157-158.

32. The diagnostic criteria also requires that the arthritis be "in one or more joints." P. Ex. 36. Arthritis is defined as "swelling or effusion, or the presence of two or more of the following signs: limitation of range of motion, tenderness or pain on motion, and increased heat." *Id.*

33. Dr. McCurdy believes the criteria is not absolute but provides necessary parameters for diagnosing JRA since its etiology is unknown. Tr. at 15. She bases her opinion that Kalynn meets a strict interpretation of the criteria on the diagnostic factors relating to age, joint involvement, and persistence of the arthritis, not on the final criteria, which requires the exclusion of other forms of juvenile arthritis. P. Ex. 31b at 1-2.

34. Dr. McCurdy's belief that Kalynn's initial symptoms represented a local reaction is further weakened by her testimony that, while it is possible for patients to experience a couple weeks of pain following vaccination, *worsening* in the second week is unusual. Tr. at 73. Dr. McCurdy's August 7 progress entry states Kalynn "got worse over the next week"; this description follows her notes regarding Kalynn's first week after the inoculation and precedes her discussion of the symptoms at weeks three and four. Tr. Ex. at 20. Dr. McCurdy confirmed her records showed that Kalynn worsened in the second week after the inoculation. Tr. at 72.

35. Incidentally, a second whole body bone scan, conducted October 11, 1994, was also normal. P. Ex. 9 at 192; s*ee also* P. Ex. 39 (Dr. Hertsgaard's October 17, 1997, review of Kalynn's July 28, 1994, bone scan, finding the study normal).

36. Dr. McCurdy testified, as referenced earlier, *supra, at footnote 12,* that patients with atypical symptoms *would not be diagnosed* with juvenile rheumatoid arthritis. Nevertheless, Dr. McCurdy used JRA as her working diagnosis throughout much of Kalynn's treatment, even after she seemingly questions the typical nature of Kalynn's JRA.

37. Several records prepared *during* Kalynn's hospitalization reference a complaint of low back pain or signs of such on examination. *E.g.*, Tr. Ex. at 3, 12, 20, 25; P. Ex. 4 at 50, 59. However, no records state specifically that Kalynn experienced low back pain on or about July 18, 1994, the date Dr. McCurdy relies on to support her opinion of an atypical presentation. More importantly, the records also fail to support Kalynn suffered low back pain in the one to two days following the inoculation, which I have already determined is the accepted date of onset of Kalynn's symptoms. *See also, supra, at footnote 15*. In addition, Dr. McCurdy testified, as cited earlier, that the parents' description of Kalynn's discomfort during diaper changes evidenced a change in Kalynn's pain from the muscle to the joint areas on or about July 18. Tr. at 49. However, Mrs. Haynes' testimony and the medical records support that Kalynn's discomfort during diaper changes began within one to two weeks following the vaccination, well before Dr. McCurdy's date of onset of Kalynn's joint problems, on July 18, 1994.

38. During the January 20, 1998, hearing, Dr. McCurdy was obviously unclear that Kalynn's rash began *five weeks* after the vaccination, during her hospitalization. Tr. at 151-153. When confronted with her

mistake, Dr. McCurdy related, nevertheless, that the infectious disease physician considered Kalynn's rash post-vaccinal or post-infectious. *Id.* at 51, 73-74, 153. She further posited that the cause or source of rashes is difficult to ascertain. *Id.* at 74.

39. Dr. Lipnick testified that morning stiffness is a "useful discriminator between JRA and infection-related arthritis." Tr. at 101.

40. The separate diagnoses of post-vaccinal arthritis and JRA are further supported by Dr. McCurdy's statement: "Although this could have been triggered by the rubella vaccination, I think that this has persisted for too long *to be strictly a post rubella vaccination synovitis*." P. Ex. 5 at 127 (Emphasis supplied).

41. Pointedly, Dr. McCurdy initially recorded "Pauci JRA" on June 24, 1997; however, this was crossed out and arthritis listed as the diagnosis. P. Ex. 38 at 554.

42. Coincidentally, Dr. McCurdy's first expert report in this matter was prepared March 1, 1996.

43. Dr. McCurdy testified on the need to exclude other diagnoses when evaluating the JRA criteria. Tr. at 18. In describing these other diagnoses, she stated: "What that would be, of course, is infectious or post infectious as best as can be done, although I think many of us do believe juvenile rheumatoid arthritis is a post infectious picture, but *at any rate at least you cannot define what that infection has been* and exclude, of course, malignancy or other types of metabolic problems that would also cause the symptoms of arthritis." *Id.* (Emphasis supplied). Her own testimony confirms that if you can define an infection as the cause of the arthritis, *e.g.*, arthritis caused by a post-vaccinal rubella infection, then such a case would be excluded from meeting the JRA diagnostic criteria.

44. A discussion of petitioners' expert's opinion, that the vaccination *caused* Kalynn's chronic arthritis, sounds like a causation-in-fact analysis, inappropriate in assessing petitioners' Table injury claim where causation is presumed given certain findings. But, at issue is whether Kalynn's arthritis is JRA or something different, *i.e.*, in this case, rubella-associated arthritis. Therefore, I am necessarily obligated to review both of Dr. McCurdy's opinions in the context of the standards governing Table injury claims.

45. Incidentally, petitioners' counsel stated in his closing arguments that "everyone agrees, in any event, that a known cause for arthritis in a particular juvenile, such as a vaccine-induced arthritis, renders the label JRA inapplicable by definition." P. Brief at 7, fn. 5. Even were I to accept Dr. McCurdy's opinion that JRA could include rubella-associated arthritis cases, there simply is no evidence to support a finding that the rubella vaccine causes JRA in children. *See Muchnick* at 10, fn. 12; *see also* the discussion, *infra*, at pages 29-31.

46. Dr. McCurdy testified that it takes two to three weeks after an initiating event, whether it be a vaccination or an infection, to manifest noticeable symptoms. Tr. at 171. Dr. McCurdy explained that it takes this long for the body "to make antibodies to that virus or to that protein that's caused the initiating event." *Id*.

47. On August 10, 1994, the Children's Hospital notified the county health department of Kalynn's aseptic meningitis. Tr. Ex. at 24.

48. In Dr. Streng's September 8, 1994, letter to Dr. Corsino, he states: "Presently, it is felt that her problems are related to her recent MMR, especially the Rubella part of her MMR. *She is having further studies performed related to this by Dr. Cherry at UCLA, in addition. Hopefully we will be able to make a firm diagnosis once this is performed* in the best interest of this child who has been going through

difficult times." P. Ex. 17 at 354 (Emphasis supplied). Dr. McCurdy noted in her September 14, 1994, letter to Dr. Corsino that Dr. Cherry's culture results were negative, although she was awaiting the final report. P. Ex. 5 at 126.

49. *See also* Dr. Lang's record that Kalynn possibly has "arthralgia/arthritis related to rubella" although he notes this is "*unusual in this age group*." Tr. Ex. at 18 (Emphasis supplied).

50. *See* my discussion of the literature in the context of the causation-in-fact claims, *infra*, at pages 28-32.

51. Dr. McCurdy's inconsistent expert reports and testimony illustrate the difficulties faced in this case in pinning down her opinions. While she ultimately testified more probably than not that Kalynn's arthritis is vaccine-related, her earlier opinions are insufficient to establish causation. *See Lacour v. Secretary of HHS*, No. 90-316V, 1991 WL 66579 (Cl. Ct. Spec. Mstr. Apr. 15, 1991)("Expert medical testimony which merely expresses the possibility--not the probability--of the occurrence of a compensable injury is insufficient, by itself, to substantiate the claim that such an injury occurred. *Strother v. Secretary of HHS*, 18 Cl. Ct. 816, 821-822 (1989), *decision foll. remand*, 21 Cl. Ct. 365, 370-373 (1990)."); *see also Muchnick v. Secretary of HHS*, No. 90-703V, 1991 WL 217673 (Cl. Ct. Spec. Mstr. Oct. 10, 1991) (expert testimony that symptoms were "consistent" with rubella induced arthritis was insufficient to establish causation); *Van Epps v. Secretary of HHS*, 26 Cl. Ct. 650 (1992)(ruling the special master did not err in finding that the petitioner had failed to establish actual causation by a preponderance of evidence where her expert found causation "highly possible.").

52. I am aware that numerous records from Dr. McCurdy and other treating physicians questioned the relationship between or even associated Kalynn's arthritis to her rubella vaccination. *E.g.*, Tr. Ex. at 18, 19, 21, 26; P. Ex. 38 at 425, 426, 427, 432, 438, 468, 475, 497; P. Ex. 4 at 121; P. Ex. 5 at 125, 127, 134; P. Ex. 17 at 347, 354. However, this relationship never seems to "take hold" and JRA became the consistently referenced diagnosis as early as September 14, 1994, when Dr. McCurdy indicated the vaccination was considered but rejected, and then provided clear, stated reasons for diagnosing pauciarticular JRA. P. Ex. 38 at 437-438; *see also Id.* at 435; *compare* P. Ex. 17 at 354 *with* P. Ex. 17 at 355. It is also around this time period that the records first reflect the negative results of Kalynn's rubella titer testing. Even later references to the MMR's role, such as the November 1994 filing of the VAERS report or Dr. McCurdy's June 1995 letter to Dr. Kramer, are overshadowed by the JRA diagnosis which appears firmly in place until April 1996.

53. This finding is in line with other Program cases which addressed the issue of whether JRA may be causally linked to the rubella vaccination. *See Muchnick* at 10, fn. 11 and 12; *see also Carter v. Secretary of HHS*, No. 89-80V, 1990 WL 293453 (Cl. Ct. Spec. Mstr. June 27, 1990), *aff'd* 21 Cl. Ct. 651 (1990); *Boehmer v. Secretary of HHS*, No. 90-317V, 1991 WL 242995 (Cl. Ct. Spec. Mstr. Oct. 31, 1991), *remanded by order* (Jan. 10, 1992); *Poulos v. Secretary of HHS*, No. 90-2315V, 1994 WL 470622 (Fed. Cl. Spec. Mstr. Aug. 17, 1994).

54. Two articles submitted by petitioners are completely irrelevant. One provides a case report of a young boy who received only a mumps-measles vaccination. P. Ex. 34. The other reviews a 41 year old woman's arthritic symptoms following a rubella infection which she contracted from her son, not from a vaccination. P. Ex. 35.

55. Incidentally, only 8 of the 19 children in the study had been diagnosed with either pauciarticular (6) or polyarticular (2) JRA prior to the study, and none had been vaccinated immediately before the onset of their symptoms or even within one year before the study. P. Ex. 28 at 1117. Moreover, none of the children (boys or girls) were Kalynn's age at the time of the study or at the onset of their symptoms. *Id.* at 1117, 1118.

56. There simply is no evidence that the rubella vaccination can be "a substantial factor in bringing about the injury" of JRA, or that the vaccination was a substantial factor in this case in bringing about Kalynn's arthritic condition, since the experts agreed a rubella reaction would not begin within one to two days following vaccination. *See Shyface v. Secretary of HHS*, ___ F.3d ___, 1999 WL 11564, *10 (Fed. Cir. 1999).

57. Dr. McCurdy essentially bases her opinion, that the rubella vaccine may be associated with persistent arthritis in children, on the literature which reports the development of chronic arthritis in non-juvenile patients, especially women, following vaccination. Tr. at 33.

58. Dr. McCurdy noted in her June 5, 1996, expert report that "the exact relationship between rubella and *chronic* arthritis is yet unproven." P. Ex. 31a at 2 (Emphasis supplied). She further stated "[s]everal *yet unproven* research studies do suggest that rubella is important in initiating chronic arthritis." *Id.* (Emphasis supplied).

59. Since I find that no vaccine-related injury occurred, I cannot conclude that any expenses incurred on behalf of Kalynn were vaccine-related.