

No. 97-89V

(Filed: November 18, 1998)

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JESSICA MUCHNICK, a minor, by and through  
LESLI MUCHNICK, as mother, and MICHAEL  
MUCHNICK, as father

*Petitioners,*

v.

National Vaccine Injury Compensation  
Program; vaccine injury table exclusion;  
agency statutory authority.

SECRETARY OF THE DEPARTMENT OF  
HEALTH AND HUMAN SERVICES,

*Respondent.*

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*Jonathan P. Sexton*, Conyers, Georgia, appeared for Petitioners.

*Vincent Matanoski*, U.S. Department of Justice, Washington, D.C., appeared for Respondent with whom  
were *Assistant Attorney General Frank W. Hunger*, *Director Helene M. Goldberg*, *Deputy Director  
John Lodge Euler*, and *Assistant Director Gerard W. Fischer*, United States Department of Justice,  
Washington, D.C.

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OPINION

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BRUGGINK, *Judge*.

Jessica Muchnick, by and through her parents, Leslie and Michael Muchnick ("Petitioners"), seeks review of the Special Master's decision in *Muchnick v. Secretary of Health & Human Services*, No. 97-89V (Fed. Cl. Spec. Mstr. July 15, 1998), denying her claim under the National Vaccine Injury Compensation Program ("the Program") pursuant to 42 U.S.C. §§ 300 aa-10 to -34 (1994). Petitioners assert that Jessica suffered from "chronic arthritis," a vaccine table injury, as the result of a vaccine for measles, mumps and rubella ("MMR"). They further argue that the Department of Health and Human Services ("Department") exceeded the scope of its authority by using Juvenile Rheumatoid Arthritis ("JRA") as an exclusionary criteria and that the Special Master abused his discretion by determining that Jessica had JRA. The matter has been fully briefed and orally argued. For the reasons set forth below, the decision of the Special Master is affirmed.

## BACKGROUND

The record developed before the Special Master is summarized below. On August 1, 1988, at the age of fifteen months, Jessica Muchnick received an MMR vaccination. Approximately three days later, Petitioners noticed that Jessica was limping or favoring her left leg. When they took her for a medical evaluation on August 11, the physician noted a swelling in her left knee. Since then, Jessica has suffered from chronic arthritis.

On July 27, 1990, Petitioners filed a Program Petition on behalf of Jessica in which they alleged that her MMR vaccination caused her arthritis. Because arthritis was not a vaccine table injury at that time, Petitioners had the burden of proving causation. After having reviewed medical records and testimony, the Special Master determined that Petitioners' evidence was insufficient to prove causation. On October 10, 1991, judgment was rendered against Petitioners and in favor of Respondent. *See Muchnick v. Secretary of HHS*, No. 90-703V, 1991 WL 217673 (Cl. Ct. Spec. Mstr.).

Subsequent to that decision and pursuant to its statutory authority under 42 U.S.C. § 300aa-14(c)(1), on March 10, 1995, the Department revised the Vaccine Injury Table. The revision established "chronic arthritis" as a new vaccine table injury related to the MMR vaccination if incurred under certain circumstances. 60 Fed. Reg. 7678 (1995); 42 C.F.R. § 100.3(a)(IV)(B) and § 100.3(b)(6). In addition, the regulation allowed otherwise stale claims to be reasserted as table injury claims. Simultaneously, however, the Department excluded certain conditions from being considered chronic arthritis, one was juvenile rheumatoid arthritis. Petitioners filed a new petition on February 10, 1997, pursuant to 42 U.S.C. § 300aa-16(b), alleging that Jessica had suffered a vaccine table injury, "chronic arthritis," that met all of the table criteria.

On July 15, 1998, following an evidentiary hearing, Special Master Hastings concluded that although Jessica's injury would appear presumptively to fall under the table definition of chronic arthritis, it nevertheless fell within the exclusion for JRA. He went on to hold that Petitioners were legally barred from attempting to establish entitlement by direct proof of causation because of the prior ruling on that

issue in their original Program petition. He stated, however, that even if Petitioners were legally entitled to raise their "actual causation" claim, they had failed to meet their burden of proving that Jessica's MMR vaccination caused her arthritis, in part because there were no epidemiological studies demonstrating the extent of a correlation between JRA and the rubella vaccine.

## DISCUSSION

The National Childhood Vaccine Injury Act provides that the United States Court of Federal Claims has jurisdiction to undertake a review of the record of the proceedings and may thereafter --

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2) (1994). Accordingly, this court undertakes its review subject to the narrow "arbitrary and capricious" standard. *See Snyder v. Secretary of HHS*, 117 F.3d 545, 547 (Fed. Cir. 1997); *Plavin v. Secretary of HHS*, 40 Fed. Cl. 609, 614 (1998) (citing *McCarren v. Secretary of HHS*, 40 Fed. Cl. 142, 144-47 (1997)). The result is that this court will affirm the decision of a special master unless there is clear error of judgment or prejudicial misapplication of law. *See Hines v. Secretary of HHS*, 940 F.2d 1518, 1527 (Fed. Cir. 1991); *Carraggio v. Secretary of HHS*, 38 Fed. Cl. 211, 217 (1997).

Under the Program, a petitioner has two means of proving entitlement to compensation. First, the Program lists specific injuries resulting from certain vaccines which create a presumption that the petitioner's injuries were caused by the vaccine if incurred within a specific period of time. These injuries are listed under the Vaccine Injury Table pursuant to Section 300aa-14 and are known as "on-table injuries," with MMR now being one of the vaccinations covered under the Program. *See* 42 U.S.C. § 300aa-14(a)(II) (1994). Once the presumption of causation arises, the burden shifts to the government to prove by a preponderance of the evidence that the injury suffered by the petitioner was caused by another unrelated factor. *See Wagner v. Secretary of HHS*, 37 Fed. Cl. 134, 137 (1997). However, if the petitioner's condition is not listed as an on-table injury, she may still receive compensation under the Program if she can prove by a preponderance of the evidence that the vaccine actually caused her injury. *See Munn v. Secretary of HHS*, 970 F.2d 863, 865 (Fed. Cir. 1992).

In this case, the petition asserts two objections. First, Petitioners argue that when the Department amended its regulations by specifically excluding cases of JRA from the larger category of chronic arthritis, it exceeded the scope of its authority, thus violating the intent of the Program. What Petitioners actually seek is judicial review of the Secretary's exercise of her authority to promulgate regulations modifying the Vaccine Injury Table pursuant to 42 U.S.C. § 300aa-14(c). Petitioners argument focuses on Section 300aa-13(a)(1)(B). That section provides for compensation if the court determines that "there is not a preponderance of evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition." *See id.* § 300aa-13(a)(1)(B) (1994). Factors unrelated are, in turn, defined as not including "idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." *See id.* § 300aa-13(a)(2)(A) (1994). Petitioners argue that because JRA is idiopathic or of unknown cause, it is a "factor unrelated" and therefore its exclusion is prohibited by statute. They thereby challenge the substance and validity of the amended table.

The Secretary of the Department has clearly been afforded the authority and broad discretion to amend and revise the Vaccine Injury Table when more accurate and conclusive medical data concerning vaccine-related injuries becomes available under section 300aa-14(c). In the exercise of that authority, the Secretary expanded the list of table injuries to include chronic arthritis, thus making this claim possible. As part of the extension of the table, however, JRA was excluded. In other words, the extension was limited, insofar as relevant here, to non-JRA chronic arthritis.

Assuming the validity of the exclusion, therefore, the question for the court is whether what plaintiff has is JRA. Petitioners, however, want to challenge the limitation built into the table expansion. The nature of this objection raises a fundamental difficulty. Under the Program, a petition challenging the adoption of regulations revising the table must be filed in a United States court of appeals within sixty days of the promulgation of such regulation, or after such date if the petition is based solely on grounds that arise after the sixty-day time period. *See* U.S.C. § 300aa-32 (1994). Such challenges cannot be brought in this court. *See Terran v. Secretary of HHS*, 41 Fed. Cl. 330, 334 (1998); *O'Connell v. Secretary of HHS*, 40 Fed. Cl. 891, 895 (1998). Petitioners thus raise their challenge too late and in the wrong court. Accordingly, this court lacks jurisdiction to decide the issue of the validity of the regulation.

The court must therefore take as a given the validity of the exclusion of JRA from the list of table injuries, under 42 U.S.C. § 300aa-14(c). Although it is true that "factors unrelated" excludes injuries of idiopathic or unknown causes, this court need not address that inquiry since Respondent does not advance JRA as a factor unrelated. *See id.* § 300-13(a)(1)(B). Therefore, the JRA exclusion remains consistent with the underlying statute and the sole issue at hand is whether Jessica initially suffered a table injury.

Petitioners also contend that the Special Master erred by abusing his discretion in determining that Jessica did not have chronic arthritis within the meaning of the table, but instead was suffering from JRA. Although we have jurisdiction to hear this argument, it nevertheless fails. There was no dispute that Jessica had ongoing arthritis and that her condition presumptively met the criteria set forth under 42 C.F.R. § 100.3(b)(6)<sup>(1)</sup> (1995) for "chronic arthritis." However, after a careful consideration of the evidence, the Special Master concluded that Jessica's condition fell within the regulation's categorical

exclusion of JRA.

The American College of Rheumatology recognizes JRA as a category of arthritis for classification purposes. A case of arthritis is classified as JRA if certain criteria are met. The three symptoms discussed in the Special Masters opinion as onset criteria for JRA were: 1) the patient was younger than sixteen years of age at the onset; 2) the arthritis lasted longer than six weeks; and 3) other forms of juvenile arthritis had been excluded.<sup>(2)</sup> The issue in dispute before the Special Master was whether the third criteria applied in Jessica's situation, i.e. whether other forms of juvenile arthritis had been excluded. The Special Master relied on the testimony of Respondent's expert witness, Dr. Carlos Rosé, a pediatric rheumatologist, who pointed out that no definite cause for Jessica's arthritis had been determined, nor could her condition be attributed to any other recognized diagnostic categories of juvenile arthritis. In his opinion, Jessica's condition fell within a fairly common subset of JRA present in young girls whose condition includes one swollen knee and a positive reading for the antinuclear antibody ("ANA"). Dr. Rosé stated that he would have classified Jessica's condition as JRA in his own practice and testified that eighty percent of his JRA patients exhibited these particular symptoms.

The Special Master carefully weighed the testimony of Petitioners' expert witness, Dr. Jerry Jacobs. Dr. Jacobs conceded that, absent the vaccination, Jessica's condition would have been classified as JRA. He argued, however, that Jessica's arthritis was causally related to the vaccination because the onset of arthritis occurred shortly after the inoculation and because all other forms of juvenile arthritis could not be excluded in this case. In substance, his testimony was that Jessica's case should have been viewed as a different form of juvenile arthritis simply because of the prior vaccination. It thus would have failed the final exclusionary criterion - "other forms of juvenile arthritis have been excluded." Dr. Rosé, however, countered by testifying that there is no recognized form of juvenile arthritis known as rubella-vaccine-induced chronic arthritis in children and that there is insufficient proof to indicate that the rubella vaccine causes juvenile chronic arthritis. Therefore, Dr. Rosé concluded it would be "highly unorthodox" to classify a case of juvenile arthritis as outside the JRA category because of the temporal relationship between the condition of arthritis and the vaccination. In addition, he testified that Dr. Jacobs used a drug in the course of Jessica's treatment which is commonly used in patients with JRA.

The Special Master found Dr. Rosé's argument more persuasive. He had a rational basis for doing so. First, if the court were to adopt Dr. Jacobs' temporal relationship argument, it would essentially reverse the JRA exclusion with no authoritative medical explanation for doing so. In fact, Dr. Jacobs failed to provide published medical articles to support his conclusion, and his own textbook indicates that most pediatric rheumatologists would classify Jessica's case as JRA. Second, Jessica's medical records demonstrate that her condition was considered to be JRA by her then attending physicians, Dr. Roberto Warman and Dr. Jacobs. Furthermore, Dr. Rosé's testimony indicated that Jessica's treatment was consistent with the course of treatment for JRA patients by rheumatologists.

A reviewing court's function is quite limited in cases where witness credibility and the relative weight given to conflicting evidence are at issue. The record reflects that the Special Master based his conclusion on the evidence of the record as a whole, and considered all of the alleged symptoms

suffered by Jessica. The Special Master articulated a rational basis for concluding that Jessica suffers from JRA. In sum, there is no indication that the Special Master acted arbitrarily or erred in making his conclusion.

## CONCLUSION

For the reasons stated above, the decision of the Special Master is affirmed.

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ERIC G. BRUGGINK

Judge

1. The term "arthropathy" is used to describe both arthritis and arthralgia. Arthritis consists of joint pain or stiffness that is accompanied by objective indications such as redness or swelling. Arthralgia, on the other hand, is used to describe joint pain or stiffness where there is no objective criteria present. *See Wagner*, 37 Fed. Cl. at 137. Here, Jessica had no history of arthropathy prior to the MMR vaccination and has medical documentation of both the onset of objective signs of acute arthritis within 42 days after the vaccination and persistence of continuous arthritis for more than six months following vaccination.

2. *See* James T. Cassidy et al., *The Development of Classification Criteria for Children with Juvenile Rheumatoid Arthritis*, 38 Bull. on the Rheumatic Diseases (Arthritis Found., Atlanta, GA.) No. 6, at 3 (1998). The Bulletin lists two other indicia: 4) Arthritis in one or more joints 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, or increased heat; 5) Type of disease onset during first six months classified as: a) Polyarthrititis (five or more joints); b) Pauciarticular disease (four or fewer joints); c) Systemic disease (intermittent fever). *See id.* The parties apparently did not dispute that these additional indicia of JRA were present.