

In the United States Court of Federal Claims

No. 00-759 V
(Filed December 7, 2004)

ROSE CAPIZZANO,
Petitioner,
v.
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.
National Childhood Vaccine Injury Act, 42 U.S.C. § 300 aa-1 et seq.; hepatitis B vaccination; rheumatoid arthritis; causation-in-fact; preponderance of evidence; Review of Special Master’s Decision.

Ronald Craig Homer, Boston, Massachusetts, for petitioner.

Ann K. Donohue, Washington, D.C. with whom was, Assistant Attorney General Peter D. Keisler, for respondent.

OPINION

MEROW, Senior Judge

Petitioner, Rose Capizzano, seeks review of the June 8, 2004 Decision by the Chief Special Master denying her Petition for Compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-1 et seq. Petitioner’s claim for compensation stems from a hepatitis B vaccination she received on May 3, 1998 and the subsequent diagnoses that she suffers from rheumatoid arthritis (“RA”).

From among the petitions filed in this court, and pending before special masters, seeking compensation based on the assertion that the hepatitis B vaccine caused RA, five were selected as “test” cases to be joined for a consolidated hearing before the Chief Special Master on the general issue of whether the hepatitis B vaccine can in fact cause RA. The joint hearing also encompassed separate consideration of causation with respect to each petitioner. In addition to the instant case, the petitions so selected were: Ashby v. HHS, 01-221 V; Analla v. HHS, 99-609 V; Ryman v. HHS, 99-591 V; and Manville v. HHS, 99-628 V.

At the two-day joint hearing held on these matters in June of 2003, the Chief Special Master initially received testimony from four expert witnesses on the general question whether hepatitis B vaccine can cause RA. Petitioners' expert testimony was presented by Dr. David Bell of St. Joseph's Health Center, London, Ontario Canada. Dr. Bell holds a Royal College Fellowship in internal medicine, the Canadian equivalent to Board Certification in the United States. He is a rheumatologist and has conducted research and has published in the area of RA. Dr. Bell's testimony set forth a medically/scientific-based mechanism explaining how the hepatitis B vaccine can cause RA in potentially susceptible individuals.

Respondent's experts who testified at the joint hearing were: Dr. Burton Zweiman, an immunologist who has been a Professor of Medicine at the University of Pennsylvania since 1963 and served for twenty-four years as Chief of the Allergy and Immunology Division; Dr. Paul A. Phillips, who holds Board Certification in internal medicine and rheumatology, and is associated with the University of New York, Upstate Medical University, Syracuse, New York where he was division head of rheumatology responsible for the research, teaching, and clinical practice program, and now does a clinical practice of rheumatology and teaches; and Dr. Lawrence Moulton who obtained his Doctorate from Johns Hopkins in biostatistics where he is employed as an Associate Professor in the University's Bloomberg School of Public Health. Respondent's experts presented testimony challenging Dr. Bell's proposed mechanism by which RA is asserted to be caused by hepatitis B vaccination.

Following the joint hearing and post-hearing submissions by the parties the Chief Special Master issued decisions denying compensation in each of the test cases. The Chief Special Master found that hepatitis B vaccine can cause RA, based mainly on record evidence, such as respondent's Exhibit L, "Rheumatic Disorders Developed After Hepatitis B Vaccination" showing cases in which patients with RA had worsening conditions after a further vaccine injection. This is referred to as "rechallenge," and the Chief Special Master relied on the Institute of Medicine's position that rechallenge is strongly probative of a causal relationship. This was also confirmed by the testimony of Dr. Zweiman and Dr. Moulton.

While the Chief Special Master found that hepatitis B vaccination can cause RA, compensation was denied to each petitioner in separate decisions on the basis that causation-in-fact was not established by the record evidence. With the exception of *Ashby*, where a judgment was entered dismissing the Petition on October 20, 2003,

Motions for Review of the Chief Special Master's Decisions were filed and randomly assigned by the clerk to judges of this court for further action.

On November 24, 2004, the assigned judge in *Manville* filed a comprehensive opinion sustaining the Chief Special Master's Decision in that case. To the extent the *Manville* Opinion addresses general issues applicable to the test cases, the undersigned agrees with the analysis and adopts those *Manville* conclusions to the extent relevant herein.

Accordingly, this Opinion will address those issues, presented by the Motion for Review, which are specific to Rose Capizzano's case.

FACTS

The Chief Special Master's June 8, 2004 Decision denying compensation states that "The facts of this case are not in dispute." (Dec. at 2.) Both parties in their submissions agree that the facts are not in dispute. However, on the initial page of petitioner's Motion for Review, petitioner states that Rose Capizzano was in good health until on May 3, 1998, at 31 years of age, she received her second hepatitis B vaccination at her place of employment, Westerly Hospital in Westerly, RI.

The Chief Special Master's Decision does not include any findings concerning petitioner's health prior to May 3, 1998, but the record contains considerable evidence, consisting of medical records, showing a history of frequent medical interventions and some level of disability in the decade before May 3, 1998. This includes a record of carpal tunnel release surgery in June of 1997, which Dr. Phillips testified can be caused by inflammation in the wrist area which, in turn, can be caused by RA. (Tr. June 12, 2003, at 363-366.) Were petitioner's health prior to May 3, 1998 relevant, the facts would be in dispute, but the issues in this case center around the petitioner's condition post-vaccination, not pre-vaccination.

As to post-vaccination condition it is undisputed that petitioner developed a serum sickness illness immediately following her second hepatitis B vaccination on May 3, 1998. There is no evidence in the record as to petitioner's first hepatitis B vaccination and any reaction or lack of reaction therefrom. The serum type sickness petitioner developed after the May 3, 1998 vaccination is cited at page 2 of the Chief Special Master's June 8, 2004 Decision which notes that petitioner developed a rash

on her abdomen and stiff and painful joints. There is no finding tying this serum sickness to RA. Petitioner's expert, Dr. Bell, testified that a serum type sickness such as that reported for petitioner can be transient, ". . . although sometimes, serum sickness reactions can be prolonged." (Tr. of June 12, 2003, at 326.)

On October 1, 1998, some five months after her vaccination, petitioner sought an evaluation by a rheumatologist, Dr. Scott Toder, who apparently raised a question as to the existence of RA. This was followed by an evaluation by another rheumatologist, Dr. Peter Himmel who prescribed gold treatments. In June of 1999, petitioner was seen by another rheumatologist, Dr. Virginia Parker, who transmitted a report (Pet'r's Ex. No. 7, dated June 14, 1999.) to the Beacon Mutual Insurance Company, for worker's compensation purposes. In her report, Dr. Parker stated, "Mrs. Capizanno (*sic*) has a mild inflammatory arthritis. Her symptoms and physical examination would be compatible with early rheumatoid arthritis." Dr. Parker also noted in her report that, "Vaccination has been associated with the onset of an acute arthritis. However, this is generally associated with live vaccines given to either the patient or the patient's young children. Mrs. Capizanno's (*sic*) children were not vaccinated anywhere around that time." Dr. Parker ended her report with the observation, "If this turns out to be rheumatoid arthritis, we are looking at a lifelong illness."

In July and August of 1999, petitioner was seen by Dr. W. Toma for evaluation of rheumatoid arthritis. In June of 2000, petitioner was evaluated by Dr. Edmund West who included in his report, "IMPRESSION: Inflammatory arthritis post vaccination." Petitioner has continued to be treated for joint pain. On March 18, 2003, Dr. Ann L. Parke of the UCONN Medical Group noted the diagnosis for petitioner of "Rheumatoid arthritis." (Pet'r's Ex. 25 at 2.)

There exists no dispute that petitioner suffers from the painful and chronic illness diagnosed as RA.

Discussion

In ruling on a motion for review of a special master's decision the options provided are: to uphold the findings of fact and conclusions of law and sustain the decision; or, to set aside any findings of fact or conclusions of law found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law

and issue the court's own findings of fact and conclusions of law; or to 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). Accordingly, the Chief Special Master's Decision may be set aside only if the findings of fact are arbitrary and capricious, the legal conclusions are not in accordance with law, or the discretionary rulings are an abuse of discretion. *Turner v. Sec'y of Health & Human Servs.*, 268 F.3d 1334, 1337 (Fed. Cir. 2001); *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

As RA is not an injury listed for the hepatitis B vaccine on the Vaccine Injury Table established pursuant to 42 U.S.C. § 300aa-14, entitlement to compensation requires that the petitioner prove, by a preponderance of the evidence, that the vaccine was not only a "but-for" cause of the RA but also a substantial factor in bringing about the RA. *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Petitioner must show a medical theory causally connecting the vaccination and RA to establish the requisite substantial factor. *Id.* at 1353. There must be a logical sequence of cause and effect showing that the vaccination was the reason for the RA. *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

In her motion for review, the petitioner takes issue with the Chief Special Master's Decision that she has not demonstrated by a preponderance of the evidence that the hepatitis B vaccine caused her RA. Initially, petitioner asserts that the Chief Special Master applied the incorrect legal standard by requiring proof in accord with the "prongs" set out in *Stevens v. Sec'y of Health & Human Servs.*, No. 99-594 V, 2001 WL 387418 (Fed. Cl. Spec. Mstr, Mar. 30, 2001). This objection is generally addressed in *Manville v. Sec'y of Health & Human Servs.*, ___ Fed. Cl. ___ (No. 99-628 V, Nov. 24, 2004) and, as previously noted, the *Manville* analysis on general issues, in the instant case, is adopted and will not be repeated here. The record demonstrates that the Chief Special Master did not confine his analysis to the *Stevens*' "prongs" but, in considering the theory of causation presented by Dr. Bell, applied the requisite Federal Circuit precedent cited above.

Petitioner asserts that, contrary to the Chief Special Master's Decision, she has shown her RA was caused by her hepatitis B vaccine by a preponderance of the evidence presented in this case. She cites evidence of a strong temporal relationship between the vaccine and her RA as set forth in medical records. Petitioner asserts that

Dr. Bell has set forth a scientific theory explaining a logical sequence of cause and effect. It is also noted that petitioner's treating doctors ascribe her RA to her vaccination, and that no other explanation for her RA has been offered.

The Chief Special Master analyzed the record evidence and in his decision explains why he concluded that petitioner failed to satisfy her burden of proof. In this regard, the temporal relationship between the vaccination and RA is accepted. This does not, however, establish causation. *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992); *See Hasler v. United States*, 718 F.2d 202 (6th Cir. 1983). Given the number of persons receiving hepatitis B vaccine and the percentage of the population developing RA, there are bound to be persons receiving the vaccine who would, in any event, develop RA. (Dec. at 30.)

With respect to Dr. Bell's scientific theory as to a mechanism whereby RA can be caused by hepatitis B vaccine, the Chief Special Master, analyzed the record evidence presented by both parties and determined that Dr. Bell's theory floundered as a result of a critical missing piece of the sequence of causation as detailed in the evidence presented by Dr. Zweiman. (Dec. at 36.) Petitioner did not obtain a third hepatitis B vaccination so that no "rechallenge" evidence was available to prove causation. (Dec. at 25.) Also epidemiological evidence, which can be used to establish a causal link between a vaccine and a particular injury, was not in existence with respect to hepatitis B and RA. *Id.*

Petitioner also objects to the Chief Special Master's determination that the statements as to causation from the medical records of doctors who examined and treated petitioner did not carry evidentiary weight. The Chief Special Master noted that the records submitted mainly state the temporal relationship of RA development after the vaccination. (Dec. at 35, fn. 42.) Examination of the medical records confirms the Chief Special Master's observation. Petitioner did not present testimony from any treating physicians and the records do not evidence any discussion as to RA causation with the exception of the brief inconclusive statement quoted previously by Dr. Virginia Parker in her report for worker's compensation purposes.

As for petitioner's observation that no explanation for her RA other than her vaccination has been offered the Chief Special Master notes that the cause of RA remains unknown as testified to by Dr. Bell and respondent's witnesses. (Dec. at 35.)

Finally, petitioner objects to the Chief Special Master's Decision that data from the Vaccine Adverse Events Reporting System ("VAERS") has extremely limited value to prove causation due to the manner in which it is collected, the lack of confirmation of the reported information and the lack of any systematic analysis. (Dec. at 33.) The decision on VAERS evidence finds record support in the testimony of Dr. Moulton.

CONCLUSION

In resolving claims under the Vaccine Act, special masters have wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence. *Whitcotton v. Sec'y of Health & Human Servs.*, 81 F.3d 1099, 1108 (Fed. Cir. 1996); *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 871 (Fed. Cir. 1992).

Based upon a review of the record evidence, including the hearing transcript of June 11-12, 2003, it cannot be determined that any findings of fact or conclusion of law by the Chief Special Master was arbitrary, capricious, or an abuse of discretion or otherwise not in accordance with law. The Chief Special Master's Decision reflects a rational analysis of the record evidence leading to a reasonable conclusion that petitioner did not prove, by a preponderance of the evidence, that her RA was caused by her second hepatitis vaccination on May 3, 1998.

Accordingly, it is **ORDERED** that the Chief Special Master's Decision, filed June 8, 2004, is **SUSTAINED** and judgment shall be entered in favor of respondent in accordance with the June 8, 2004 Decision.

James F. Merow
Senior Judge