OFFICE OF SPECIAL MASTERS

(E-Filed: October 3, 2006)
No. 99-504V
PUBLISHED

RONALD ALLEN III, a minor, by his parents and natural guardians, RONALD and JANET ALLEN,	)	Effect of omnibus proceedings on individual cases
Petitioners,	)	
v.	)	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	)	
Respondent.	)	

Order Ruling on the Effect of the Rheumatoid Arthritis Omnibus Proceedings[1]

On July 26, 1999, petitioners, Ronald and Janet Allen, as parents and natural guardians of their minor son, Ronald Allen III (Ronald), filed a petition pursuant to the National Vaccine Injury Compensation Program[2] (the Act or the Program). In their

[1]Because this document contains a reasoned explanation for the action of the undersigned, the document shall post on the website of the United States Court of Federal Claims in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has fourteen days within which to request the redaction "of any information furnished by that party (1) that is trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Rules of the United States Court of Federal Claims (RCFC), Appendix B, Vaccine Rule 18(b). In the absence of timely objection, the entire document will be made publicly available.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended,

petition, petitioners alleged that on October 15, 1996, Ronald received a hepatitis B vaccination and experienced an adverse reaction to the inoculation.[3] Petition (Pet.) at 1. The petition did not include "[a] fact-specific description of [Ronald's] claimed symptoms and the nature and extent of [his alleged] injuries." Id. at 1-2. However, in support of their claim, petitioners filed their respective affidavits and forty-six exhibits containing Ronald's medical records. See Petitioners' Exhibit (Ps' Ex.) 1-46 (medical records), 61-62 (parents' affidavits).

Additionally, on June 13, 2006, petitioners filed an expert report from Andrew J. White, M.D., Assistant Professor of Pediatrics, Division of Rheumatology and Immunology. Ps' Ex. 47.[4] Dr. White opined that Ronald developed systemic juvenile rheumatoid arthritis (SJRA) after receiving his hepatitis B vaccination in 1996. Id. He stated in his report that SJRA could result in a vaccinee within one to three weeks after receiving a vaccination. Id. In his one paragraph opinion letter, Dr. White set forth his theory of causation:

> Vaccines stimulate the immune system to react against antigen (Hepatitis B in this case). Occasionally, the immune response of the vaccine recipient cross-reacts with the recipient's own tissues. If these tissues are the joints, for example, [S]JRA can result. . . . [S]uch reactions are generally more developed or severe on subsequent vaccinations.

Id.

During a status conference on June 28, 2006, petitioners' counsel asserted his position that the findings of the rheumatoid arthritis omnibus proceedings were applicable

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42 U.S.C.A. § 300aa-10-§ 300aa-34 (2000 & West Supp. 2002) (Vaccine Act or the Act). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

[3] The hepatitis B vaccine is "a noninfectious viral vaccine derived by recombination from hepatitis B surface antigen and cloned in yeast cells; administered intramuscularly for immunization of children and adolescents and of persons at increased risk for infection." Dorland's Illustrated Medical Dictionary 1999 (30th ed. 2003).

[4] On August 13, 2001, petitioners filed their respective affidavits as petitioners' exhibits 47 and 48. Ps' Ex. 47 (father's affidavit); Ps' Ex. 48 (mother's affidavit). Subsequently, on June 13, 2006, petitioners filed the expert opinion of Dr. White and his curriculum vitae (CV) as petitioners' exhibits 47 and 48. Ps' Ex. 47 (Dr. White's opinion); Ps' Ex. 48 (Dr. White's CV). For reference clarity, the undersigned uses parenthetical descriptions of the filings.

in this case because Ronald suffers from rheumatoid arthritis as a result of a hepatitis B vaccination. By order dated July 10, 2006, the undersigned directed the parties to brief their respective positions on the effect of the rheumatoid arthritis omnibus proceedings on this case.

Now before the undersigned are petitioners' Memorandum on the Effect of the Rheumatoid Arthritis Omnibus Proceedings (Ps' Mem.) and respondent's Response to Petitioners' Memorandum on the Effect of the Rheumatoid Arthritis Omnibus Proceedings (R's Resp.). The issue is ripe for a ruling.

I. The Rheumatoid Arthritis Omnibus Proceedings

After the filing of this petition for compensation in 1999, petitioners' counsel, along with counsel from the law firm of Conway, Homer & Chin-Caplin, and respondent's counsel agreed to litigate as "test cases" five of the numerous filed Vaccine Act claims alleging an injury of rheumatoid arthritis following a hepatitis B vaccination.[5] Ps' Mem. at 2. The Chief Special Master conducted a joint hearing in the test cases on the general issue of whether the hepatitis B vaccine can in fact cause R[heumatoid]A[rthritis]." Capizzano v. Secretary of HHS, 2004 WL 1399178 (Fed. Cl. Spec. Mstr. June 8, 2004) (Capizzano II). The proceedings in connection with these test cases are referred to as the Rheumatoid Arthritis Omnibus Proceedings.

As described in Capizzano II,[6] one of the designated test cases for the Rheumatoid Arthritis Omnibus Proceedings, this "omnibus" process involved:

> litigat[ing] [the test cases] at a [joint] hearing to determine the general issue of whether the hepatitis B vaccine can cause R[heumatoid]A[rthritis]. Evidence was also heard on the issue of specific causation in each test case.

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[5] Petitioners' counsel selected the five test cases as "the most representative of all the cases filed." Capizzano v. Secretary of HHS, 2004 WL 1399178, at *1 (Fed. Cl. Spec. Mstr. 2004) (Capizzano II).

[6] In Capizzano II, the Chief Special Master concluded that petitioner "failed to establish that the rheumatoid arthritis . . . from which [petitioner] suffers was caused by an injection of hepatitis B vaccine that she received." Capizzano v. Secretary of HHS, 440 F.3d 1317 (Fed. Cir. 2006) (Capizzano IV) (citing Capizzano II, 2004 WL 1399178, at *1). On appeal, the United States Court of Appeals for the Federal Circuit vacated and remanded this decision. See Capizzano IV, 440 F.3d at 1319.

> A finding on the issue of general causation would then be used in each of the remaining RA cases as a basis for determining whether or not the vaccine caused the injury alleged in that particular case.

Id. at *1 (emphasis added).

Special masters have conducted omnibus proceedings to facilitate deciding the issues of causation when: (1) multiple petitioners file claims for Program compensation; (2) the petitioners allege the same or substantially the same injury; (3) the petitioners allege that the injury resulted from the administration of the same type of vaccination; and (4) the parties are aware of the special master's intention to use omnibus proceedings to hear evidence and to make findings. Additionally, the special masters have addressed the effect of omnibus proceedings on individual cases in the Vaccine Program.

Consistent with the view expressed in Capizzano I is the view recently expressed in a "Ruling Concerning 'Entitlement Issue'" issued in the case of Berry v. Secretary of HHS, No. 01-556 V (Fed. Cl. Spec. Mstr. Sept. 13, 2006). Relying on the knowledge gained in omnibus proceedings to evaluate specific claims that rubella vaccinations caused arthropathy injuries,[7] the special master wrote:

> [C]ounsel for both parties have been well aware that in resolving this case I would utilize the evidence contained in the Rubella Omnibus File, and the knowledge concerning the general rubella/arthropathy causation issue that I have gained in the course of the above-described general proceedings concerning that issue. Indeed, the entire idea of the proceedings on the general issue was that information gained in those proceedings would be applied to individual cases. Moreover, petitioner's primary "causation-in-fact" argument in this case is that I should apply to her case the causation criteria developed in the proceedings concerning the general issue.
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> In this regard, I note that it seems very appropriate in Program cases that a special master will at times utilize information and knowledge gained in one Program case in order to resolve another Program case. The chief reason is the inherent nature of the factfinding system set up under the

[7] "Arthropathy" is any "joint disease." Dorland's Illustrated Medical Dictionary 156 (30th ed. 2003). In describing cases considered in the rubella/arthropathy omnibus proceeding, the special master used the term arthropathy because "it encompasses both joint pain, also known as "arthralgia," and joint swelling, also known as arthritis. Berry, slip op. at 6. See also Dorland's at 149 (defining the medical terms arthralgia and arthritis).

Program. Congress assigned this factfinding task to a very small group of special masters, who would hear, without juries, a large number of cases involving a small number of vaccines. Congress gave these masters extremely broad discretion in deciding how to accept evidence and decide cases. (See, e.g., § 300aa-12(d)(2).) Congress charged these masters to resolve such cases speedily and economically, with the minimum procedure necessary, and to avoid if possible the need for an evidentiary hearing in every case. Id.; see also H.R. Rept. No. 99-660, 99th Cong., 2nd Sess., at 16-17 (reprinted in 1986 U.S.C.C.A.N. 6344, 6357-58). Congress even specified that a master should be "vigorous and diligent in investigating" Program factual issues (H.R. Rept. 99-660, supra at 17 (emphasis added)), in an "inquisitorial" fashion (H.R. Rept. No. 101-247, at 513 (reprinted in 1989 U.S.C.C.A.N. 1906, 2239)), indicating that a master can and should actively seek out, on his own, evidence beyond that presented by the parties to a particular case. Given this factfinding system, it appears that Congress intended that the special masters would gain expertise in factual issues, including "causation-in-fact" issues, that would repeatedly arise in Program cases. It appears that Congress intended that knowledge and information gained by the masters in the course of Program cases would be applied by the masters to other Program cases, when appropriate. A number of published opinions have recognized that this Congressional intent is implicit in the factfinding system devised by Congress. See, e.g., Ultimo v. Secretary of HHS, 28 Fed. Cl. 148, 152-53 (1993); Loe v. Secretary of HHS, 22 Cl. Ct. 430, 434 (1991).

The idea of utilizing an "omnibus proceeding" to gather information applicable to a significant number of Program cases, therefore, would seem to fit clearly within this Congressional intent. This procedure not only allows a special master to bring special expertise to particular cases, but also helps the Program to accomplish the Congressional goals of speedy and economical resolution of cases. This general procedure, therefore, has been utilized not only in the "rubella arthropathy" cases before me, but also for two other large groups of cases, i.e., the "poliomyelitis" cases before Chief Special Master Golkiewicz (see, e.g., Gherardi v. Secretary of HHS, No. 90-1466V, 1997 WL 53449 (Fed. Cl. Spec. Mstr. Jan. 24, 1997)) and the "tuberous sclerosis" cases before Special Master Millman (see, e.g., Costa v. Secretary of HHS, 26 Cl. Ct. 866, 868 (1992)). This general procedure is also currently being utilized, at the request of the petitioners, in the "thimerosal/autism" cases currently pending before me (see the Autism General Order #1, 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002)).

> Of course, the special masters managing these groups of cases have also taken care to ensure that the rights of individual petitioners to fair resolution of their cases is not lost in the efficiency of an "omnibus proceeding." For example, before, during, and after the general proceedings that I have conducted concerning this rubella/arthropathy causation issue, I have stressed to all counsel in the rubella/arthropathy cases that each party in each individual case has the right to offer additional relevant evidence, and to challenge the validity of the evidence received during the "omnibus proceeding."
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> Given the above-described Program factfinding system devised by Congress, accompanied by the procedural safeguards for individual cases described above, I am satisfied that it is appropriate for me to utilize the evidence gained in the "omnibus proceeding" in resolving individual petitioners' cases. Neither the respondent, nor any petitioner in any individual Program case, has ever argued otherwise.

Id. at 14-15 n.16.

Based on the broad discretion afforded special masters in the determination of how to accept evidence and to decide cases, see § 300aa-12(d)(2), and based on the Congressional charge to resolve Program cases with speed and economy, id.; see also H.R. Rep. No. 99-908, 99th Cong., at 16-17 (reprinted in 1986 U.S.C.C.A.N. 6344, 6357-58), the undersigned concurs with the previously expressed views that omnibus proceedings are a permissible method of hearing evidence and making factfindings in Program cases. Moreover, the findings on general causation derived from omnibus proceedings may apply in specific cases. The applicability of those findings in a particular case, however, turns on a showing that the vaccinee's injury is the injury contemplated in the omnibus proceeding, see Rules of the United States Court of Federal Claims (RCFC), Appendix B, Vaccine Rule 8(c) (directing the special master "to consider all relevant and reliable evidence"), and that the alleged injury resulted from the same type of vaccination contemplated in the omnibus proceeding. Upon a showing in an individual case that both the vaccinee's injury and the type of vaccination received were considered in an omnibus proceeding, a special master may consider the evidentiary findings derived from the omnibus proceeding, in addition to the evidence offered in a particular case, in determining whether a particular vaccinee is entitled to Program compensation.

II. The Parties' Arguments

Here, petitioners argue that they have demonstrated, "at a minimum, the relevance of the omnibus proceedings to the instant case." Ps' Mem. at 3. Petitioners assert that Ronald "suffer[s] from RA." Id. They further assert that they have filed the expert opinion of a treating doctor and, in addition to literature supporting the expert's opinion, they have filed an article containing a case report of Ronald's condition describing "the extensive workup [that has been] performed on [Ronald] without identifying any other cause for his RA." Id. Petitioners also argue that the filed medical records indicate that the timing of the onset of Ronald's RA following his hepatitis B vaccination "was 'appropriate' under Capizzano." Id. Conceding that this case is distinguishable from Capizzano because there is no evidence of rechallenge here, petitioners explain that Ronald "reacted so strongly to [the] vaccination of 10-15-96, it was not recommended that he get a third [hepatitis B shot]." Id. at n.1. Petitioners contend that not only "have [they] clearly demonstrated the relevance . . . of the RA omnibus proceedings to the instant case," id. at 5, they also contend that they "have made their prima facie case" with respect to causation, id. Petitioners suggest that omnibus proceedings have a "'binding'" effect on individual cases. Id. at 3.

Respondent asserts that "petitioners erroneously argue that the findings in Chief Special Master Golkiewicz's entitlement decision in Capizzano should apply to this case" because Ronald does not have RA. R's Resp. at 3 (emphasis added). Respondent points out that Ronald's diagnosis is SJRA and states that "no where in the entitlement decision in Capizzano does [the decision] reference [S]JRA as a condition under consideration in the evaluation of the five test cases." Id. Respondent argues that petitioners have failed to offer any evidence "suggest[ing] that a finding with respect to RA should apply equally to a case of [S]JRA" Id.

Respondent contends that even if "petitioners are able to establish the relevance of the RA Omnibus Proceedings in this case[,] . . .[their] argument that the RA Omnibus Proceedings have a "binding" effect in other, supposedly similar cases before a different special master is an overstatement of the effect of legal precedent in the Vaccine Program." Id. at 4. Respondent, however, acknowledges that the findings made and the conclusions drawn during omnibus proceedings "may be informative or persuasive." Id.

III. Discussion

"Special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand." Guillory v. United States, 59 Fed. Cl. 121, 124 (2003) (quoting Hanlon v. Secretary of HHS, 40 Fed. Cl. 625, 630 (1998)). However, as respondent has observed, the reasoning underlying the decisions of other special masters or the Court of Federal Claims may be informative or

persuasive in a particular case. Moreover, when the considered decisions involve factual underpinnings that are substantially similar to the facts before the deciding special master, the reasoning underlying the decisions of other special masters or the Court of Federal Claims may be of particular interest to a special master. A special master's decision must reflect consideration of "all relevant and reliable evidence." RCFC, Appendix B, Vaccine Rule 8(c). Accordingly, the undersigned will consider all reliable evidence in the Rheumatoid Arthritis Omnibus Proceedings that is relevant to Ronald's case.

The undersigned's consideration of this evidence, however, does not relieve petitioners of their burden of proving by preponderant evidence that the administered hepatitis B vaccination brought about Ronald's injury. Petitioners satisfy this burden by providing: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The "logical sequence of cause and effect" proffered by petitioners must be supported by a "reputable" scientific or medical explanation. Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992); Knudsen v. Secretary of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994) (requiring that a "sound and reliable" medical or scientific explanation support a causation theory before a special master).

The Chief Special Master issued his decision in Capizzano II after conducting a two-day hearing. Capizzano IV, 440 F.3d at 1321. At that hearing, petitioner presented: (1) her affidavit addressing the timing and severity of her symptoms; (2) her medical records; (3) the diagnoses of four of her treating physicians; (4) VAERS data;[8] and (5) the expert testimony of David Bell, M.D., a rheumatologist, "concerning a mechanism by which a hepatitis B vaccine could cause rheumatoid arthritis." Id. at 1321-22; see also Capizzano II, 2004 WL 1399178, at *13 (discussing Dr. Bell's qualifications as an expert witness). Respondent presented the expert testimony of Burton Zweiman, M.D., an immunologist, Paul A. Phillips, M.D., a rheumatologist, and Dr. Lawrence Moulton, a biostatistician. Capizzano IV, 440 F.3d at 1322. See also Capizzano II, 2004 WL 1399178, at **15 nn.30-31, *21 (discussing the expert qualifications of respondent's experts). The Chief Special Master concluded "that petitioner ha[d] not demonstrated by a preponderance of the evidence that the hepatitis B vaccine caused her RA." Capizzano II, 2004 WL 1399178, at *27. The Chief Special Master added:

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[8] Petitioner presented as evidence data collected from the Vaccine Adverse Event Reporting System (VAERS) of "'several hundred [case reports] associating Hepatitis B vaccine with rheumatological reactions.'" Capizzano II, 2004 WL 1399178, at *23 (internal citation omitted).

> To be sure, petitioner has established that the hepatitis B vaccine can cause RA by presenting rechallenge cases that establish the biologic plausibility that the vaccine can cause the disease. However, no persuasive evidence establishes that the vaccine did cause petitioner's RA.

Id.

Although petitioners are able to introduce findings from the Rheumatoid Arthritis Omnibus Proceedings for consideration by the undersigned in this case, it is petitioners' onus to demonstrate the applicability of particular findings from that omnibus proceeding to Ronald's case. Moreover, not only must petitioners demonstrate how the evidence adduced in the Rheumatoid Arthritis Omnibus Proceeding is relevant to Ronald's case, petitioners must also identify, with specificity, the evidence from the Rheumatoid Arthritis Omnibus Proceeding on which they intend to rely in support of their claim of causation in this case.

Petitioners shall be prepared to address how they intend to make the foregoing showing during the next status conference in this matter scheduled to be held on **Tuesday, October 17, 2006 at 1:00 P.M. (EST).**

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
Patricia E. Campbell-Smith
Special Master