

U.S. COURT OF FEDERAL CLAIMS OFFICE OF SPECIAL MASTERS

For Background Use Only

The Autism Proceedings

- - Test Case Theories

The Petitioners' Steering Committee (PSC) has advanced three different theories of "general causation," *i.e.*, how the vaccines involved can cause autism, in the Omnibus Autism Proceeding. The Office of Special Masters (OSM) has assigned three Special Masters to resolve the autism cases. The OSM instructed the PSC to designate three "test cases" for each of the three theories, a total of nine test cases. The three theories of "general causation" are: (1) the theory that MMR vaccines and thimerosal-containing vaccines can combine to cause autism; (2) the theory that thimerosal-containing vaccines can cause autism; and, (3) the theory that MMR vaccines, without regard to any thimerosal additive, can cause autism. (However, the third theory - - whether MMR vaccines, without regard to any thimerosal additive, can cause autism - - was later dropped by the PSC since the evidence pertaining to that theory was largely presented at the Cedillo Hearing on the first theory.)

- - Hearings Conducted on the First Theory

During 2007, Hearings were conducted in the three "test cases" representing the PSC's first "general causation" theory. Specifically, in June of 2007 Special Master George Hastings presided over Cedillo v. HHS, No. 98-916V; in October of 2007 Special Master Patricia Campbell-Smith presided over Hazlehurst v. HHS, No. 03-654V, and in November of 2007 Special Master Denise Vowell presided over Snyder v. HHS, No. 01-162 V. The Special Masters' decisions in these three cases were issued on February 12, 2009.

The evidentiary Record for the three cases remained open for some time past the evidentiary Hearings. For example, following the Hearing in Cedillo, because of the importance of these cases, the parties listened to the digital recording of the proceedings and made numerous corrections to the nearly 3,000 page transcript. The final corrected transcript for Cedillo was not filed until June 11, 2008. The parties also filed nearly 500 pages of post-Hearing briefs in Cedillo. Finally, after the PSC exhausted their efforts to obtain information from similar litigation conducted in England, the Records closed on July 31, 2008 for the three cases. With the closing of the evidentiary Records, the Special Masters could begin deciding their respective cases.

Regarding all three cases, in addition to the 5,000 pages of transcript and the well over 700 pages of post-Hearing briefs, the Records in these three cases contain 939 medical articles (a typical vaccine case presents about 10), with Cedillo containing 658 (this is because the general causation testimony presented in Cedillo was applied to Hazlehurst and Snyder). Between the three (3) cases, 50 expert reports were filed and 28 experts testified - 16 in Cedillo (by contrast, a typical vaccine case presents 2-6 experts.)

- - Hearings Conducted on the Second Theory

The evidentiary Hearings in the three “ test cases” for the second theory of causation - whether thimerosal-containing vaccines can cause autism - were conducted over three weeks in May and July of 2008 in the National Courts Building in Washington, DC. Special Master George Hastings presided over King v. HHS, No. 03-589V; Special Master Patricia Campbell-Smith presided over Mead v. HHS, No. 03-215V; and, Special Master Denise Vowell presided over Dwyer v. HHS, No. 03-1202V. The parties are currently engaged in extensive post-Hearing briefing, which should conclude in the late spring or early summer of 2009. Thereafter, the three Special Masters will consider the evidence and arguments and issue their respective opinions in the cases.

- - Parties’ Right to Appeal the Special Masters’ Decisions

The Special Master’s decision in a case is final, unless within 30 days of issuance of the Special Master’s decision, a party seeks review from a United States Court of Federal Claims judge. The Court of Federal Claims judge will review the Record of the proceedings and either 1) affirm the Special Master’s findings and conclusions; 2) set aside any findings of fact and conclusions of law found to be arbitrary, capricious or an abuse of discretion; or, 3) remand the case for further action in accordance with the court’s direction.

The proceedings before the Court of Federal Claims shall be the final determination of the case, unless a party seeks review in the United States Court of Appeals for the Federal Circuit. Such petition for review must be filed within 60 days after the entry of the Court of Federal Claims judgment. Finally, a party may seek review of the Federal Circuit’s decision in the Supreme Court of the United States.

- - Sources for Additional Autism Proceedings Information

The Docket of the Omnibus Autism Proceeding is available on-line at the Court’s website at www.uscfc.uscourts.gov. From the homepage, click on the “Vaccine Info” link, and then on the “Autism Proceeding” link. The Docket of the Omnibus Autism Proceeding traces the history of the autism litigation before the Special Masters from General Order #1, filed July 3, 2002, which established and explains the Omnibus Proceeding, through the most recent Autism Update, filed September 23, 2008. The Docket is the most complete source of information regarding the Autism litigation.

For additional general information regarding the Vaccine Program, see www.hrsa.gov/vaccinecompensation.