

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) originally announced that it would advance three different theories of "general causation,"-- i.e., how vaccines can cause autism--in the Omnibus Autism Proceeding. The Office of Special Masters (OSM) 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" originally designated by the PSC were: (1) that MMR vaccines and thimerosal-containing vaccines can combine to cause autism; (2) that thimerosal-containing vaccines can alone cause autism; and, (3) that MMR vaccines alone can cause autism. Later, however, the PSC chose not to present the third theory since evidence pertaining to that theory was largely presented in the first theory test cases.

-- 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. 01-162V.

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 Great Britain, the records were closed in the three cases in late 2008. With the closing of the evidentiary records, the Special Masters began 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). Between the three cases, 50 expert reports were filed and 28 experts testified.

The Special Masters' decisions in the three test cases were issued on February 12, 2009.

-- 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 Judge of the United States Court of Federal Claims. The 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 petitioners in each of the first theory "test cases" sought review by a Court of Federal Claims Judge. In each case, a Judge affirmed the Special Masters' decision. See *Cedillo v. Secretary of HHS*, 89 Fed. Cl. 158 (2009) (Judge Wheeler); *Hazelhurst v. Secretary of HHS*, 88 Fed. Cl. 473 (2009) (Judge Wiese); *Snyder v. Secretary of HHS*, 88 Fed. Cl. 706 (2009) (Judge Sweeney).

The proceedings before the Court of Federal Claims are 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. **In two of the three first theory cases--*Cedillo* and *Hazelhurst*, the petitioners appealed to the Federal Circuit where the appeal remains pending.** In the third case--*Snyder*, no appeal was filed. Finally, a party may seek review of the Federal Circuit's decision in the Supreme Court of the United States.

-- Hearings Conducted on the Second Theory

The evidentiary hearings in the three "test cases" for the second theory of causation - whether thimerosal-containing vaccines alone can cause autism - were conducted over three weeks in May and July of 2008 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 engaged in extensive post-hearing briefing, which concluded in July 2009. The Special Masters' decisions in these three test cases were issued on March 12, 2010.

-- 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 Office of Special Masters from General Order #1, filed July 3, 2002, which established and explains the Omnibus Proceeding, through the most recent Autism Update. 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.