

ORIGINAL

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(Filed: November 28, 2007)

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U.S. COURT OF
FEDERAL CLAIMS

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IN RE: CLAIMS FOR VACCINE INJURIES
RESULTING IN AUTISM SPECTRUM
DISORDER OR A SIMILAR
NEURODEVELOPMENTAL DISORDER
VARIOUS PETITIONERS,
v.
SECRETARY OF HEALTH AND
HUMAN SERVICES,
Respondent.
\*\*\*\*\*

AUTISM MASTER FILE<sup>1</sup>

AUTISM UPDATE--NOVEMBER 28, 2007

This Update describes a number of recent developments in the Omnibus Autism Proceeding ("OAP") that have occurred since the last Autism Update, issued on September 28, 2007. Since that last Update, unrecorded telephonic status conferences were held on October 10, October 31, November 19, and November 26.

<sup>1</sup>The Autism Master File constitutes the record of the Omnibus Autism Proceeding. The complete File is maintained by the Clerk of this court, and is available for inspection by the parties. An electronic version of the File is maintained on this court's website. This electronic version contains a complete list of all documents in the File, along with the full contents of most of those documents: the exception is that the content of some documents has been withheld from the website due to copyright considerations or due to 42 U.S.C. § 300aa-12(d)(4)(A). To access this electronic version of the Autism Master File, visit this court's website at www.uscfc.uscourts.gov. Click on the "Office of Special Masters" page, then on the "Autism Proceeding" page.

### ***A. Number of cases***

At this time, about 4,900 petitions in autism cases remain pending, stayed (at the petitioners' own requests) until the conclusion of the OAP. Additional petitions continue to be filed.

### ***B. Post-hearing proceedings in the Cedillo "test case"***

As previously reported, on June 11 through June 26, 2007, we conducted an evidentiary hearing concerning the first "test case" in the Omnibus Autism Proceeding, *Cedillo v. HHS*, No. 98-916V. The parties are now in the process of preparing written briefs analyzing the evidence in the case. The petitioners filed their opening brief (263 pages) on November 12, 2007. The respondent's brief is due on January 11, 2008, and the petitioners' reply brief is due on February 11, 2008. Once the last of those briefs are filed, Special Master Hastings will issue a written ruling.

### ***C. The other two "test cases" concerning the PSC's first general causation theory***

As explained in previous Autism Updates, the PSC stated its desire to present *three different theories* of "general causation" in the Omnibus Autism Proceeding, and the presiding special masters have instructed the PSC to designate three "test cases" for *each* of the three theories. The *Cedillo* case, then, is part of the initial group of three test cases with respect to the PSC's *first* "general causation" theory. Therefore, during the June hearing, the parties presented evidence not only about the particulars of Michelle Cedillo's claim, but also about the first *general causation* theory of the PSC--that is, the *general* theory that MMR vaccines and thimerosal-containing vaccines can *combine* to cause autism.

We are pleased to report that since our last Autism Update, we have conducted evidentiary hearings for the two additional test cases concerning that first "general causation" theory. In one of those cases, *Hazlehurst v. HHS*, No. 03-654V, a hearing was held before Special Master Campbell-Smith on October 15-18, 2007, in Charlotte, North Carolina. In the other case, *Snyder v. HHS*, No. 01-162V, a hearing was held on November 5-9, 2007, in Orlando, Florida, before Special Master Vowell. After post-hearing briefs in those cases are filed, in each case the presiding special master can apply the *general causation* evidence from the June hearing to the particular case. Special Masters Campbell-Smith and Vowell will then each issue a written ruling in her own test case.

### ***D. The petitioners' additional theories of general causation***

As noted previously, the PSC proposes to present *three different theories* of "general causation." As to the PSC's first theory, that MMR vaccines and thimerosal-containing vaccines can *combine* to cause autism, we have already heard the evidence in the three "test cases" described above, the *Cedillo*, *Hazlehurst*, and *Snyder* cases. The additional two theories are (2) that thimerosal-containing vaccines alone can cause autism, and (3) that MMR vaccines alone can cause autism. We have previously instructed the parties that evidentiary hearings in three test cases in *each* of these additional two theories are to be completed by September 30, 2008.

## ***1. Second theory***

Under the procedure and schedule that we have adopted, the PSC filed into the Autism Master File, on August 28 and September 4, 2007, three *general causation* expert reports pertaining to the PSC's second theory, that thimerosal-containing vaccines alone can cause autism. On November 19, 2007, the PSC designated one "test case" concerning that theory (*Mead v. HHS*, No. 03-215V), and filed a case-specific expert report. The PSC will designate a second "test case" and file a case-specific expert report in that case by November 30, 2007, and designate a third "test case" and file an expert report in that case by December 7, 2007. The respondent is scheduled to file respondent's expert reports concerning all three cases on February 25, 2008. An evidentiary hearing, encompassing both general causation concerning the second theory, and specific causation in each of the three cases, will take place on May 12 through 30, 2008, in Washington, D.C.

## ***2. Third theory***

The PSC's third theory, as noted above, is that the MMR vaccine alone can cause autism. The schedule for that theory is as follows. The PSC will designate three test cases and file all expert reports concerning that theory and those test cases by May 5, 2008. Respondent's expert reports are due on July 28, 2008. An evidentiary hearing will be held beginning on September 15, 2008, in Washington, D.C.

### ***E. Filing of medical records, and determinations concerning timeliness of filing, in pending cases***

The Chief Special Master is also working with representatives of the respondent and the PSC concerning one other issue relating to the 4,900 pending autism cases. That is, in many of the pending cases, medical records have not been filed (see *Autism General Order #1*, p. 7), and it is therefore not clear whether those petitions were timely filed. The Chief Special Master and those counsel are working cooperatively on the issue of how to get enough records filed in the pending cases, so that determinations concerning the timeliness of filing can be made in such cases, even as the parties in the pending cases await the outcomes of the nine "test cases" described above.

***We again stress that at this time we will NOT be ordering records to be filed in ALL of the pending autism cases.*** Rather, the Chief Special Master and counsel are organizing this process in a deliberate, step-by-step manner. Initially, the PSC chose about 50 cases in which selected records were filed, sufficient to permit a determination with regard to timely filing. The Chief Special Master and the parties are currently working through those 50 cases, to see what types of issues arise.

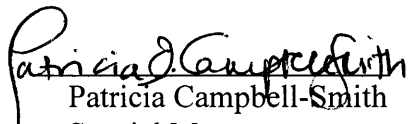
Beginning early next year, the Chief Special Master, working with the PSC and respondent's representatives, will begin selecting about 200 cases per month in which the petitioner will be required to submit selected records. Petitioner's counsel (or a petitioner proceeding without counsel) will be specifically notified by written order if his or her case has been selected, and will be given detailed instructions concerning how to file the required records. ***Unless you receive specific***

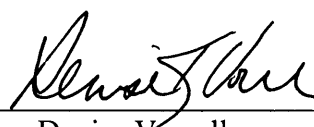
*notification from the court that your case has been selected for this process, there is no requirement to file medical records at this time.*

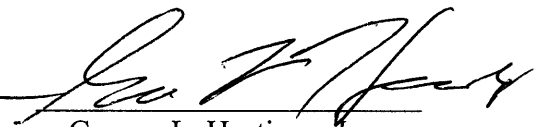
We note that the Chief Special Master, the PSC, and respondent are striving to structure this process in a way that will not overburden this court or counsel for either side. We will continue to report concerning this process in future Autism Updates.

*F. Future proceedings*

We will continue to meet regularly with the representatives of both the PSC and respondent, to plan the additional stages of the Omnibus Autism Proceeding. We will continue to issue these Autism Updates describing the process. The next status conference in the Omnibus Autism Proceeding is scheduled for December 17, 2007.

  
Patricia Campbell-Smith  
Special Master

  
Denise Vowell  
Special Master

  
George L. Hastings, Jr.  
Special Master