

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(Filed: September 28, 2007)

FILED
SEP 28 2007
U.S. COURT OF
FEDERAL CLAIMS

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 FILE¹

AUTISM UPDATE-SEPTEMBER 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 July 12, 2007. Since that last Update, unrecorded telephonic status conferences were held on July 20, August 9, September 4, and September 24.

A. Number of cases

¹The 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.

At this time, just over 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. Discovery issues

As indicated in previous Autism Updates, pursuant to two extensive discovery requests made by the Petitioners' Steering Committee (hereinafter "PSC"), which is the committee of attorneys representing the petitioners in the OAP, more than 218,000 pages from government files have been provided to the PSC. At this time, there are no discovery issues pending before us in the OAP.

C. 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 following schedule has been established for that briefing process. The petitioners will file their opening brief by October 15, 2007; the respondent will file a brief by December 15, 2007; and the petitioners will file a reply brief by January 15, 2008. Once the last of those briefs are filed, Special Master Hastings will analyze those briefs. He will study not only the 3,000-page transcript of the hearing, but also the other evidence in the record, including thousands of pages of Michelle's medical records; approximately 20 expert reports specific to Michelle's case; and the approximately 800 articles from medical journals and medical text excerpts, filed by the parties. He will then issue a written ruling in the case as soon as possible.

D. The next two "test cases" concerning the PSC's first general causation theory

As explained in previous Autism Updates, the PSC has stated its desire to present *three* different theories of "general causation" in the Omnibus Autism Proceeding. And we, 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 scheduled evidentiary hearings to hear the specific facts of the two additional test cases concerning that first "general causation" theory. One of those cases, *Hazlehurst v. HHS*, No. 03-654V, has been scheduled for trial before Special Master Campbell-Smith, to commence on October 15, 2007, in Charlotte, North Carolina. The other, *Snyder v. HHS*, No. 01-162V, will be tried on November 5, 2007, in the area of Daytona, Florida, before Special Master Vowell. After those hearings are completed and post-hearing briefs are filed, in each case the 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.

As explained above, the special masters in *Hazlehurst* and *Snyder* will each be analyzing and applying the extensive *general causation* evidence developed in the *Cedillo* case and discussed during the June hearing. The testimony to be taken during the *Hazlehurst* and *Snyder* hearings will, accordingly, focus largely upon the *specific facts* of those cases, although we expect some general causation evidence to be adduced as well. Thus, in view of the more limited nature of the general causation testimony, we expect less public interest in the specifics of these two cases than was the case with the June hearing. Nevertheless, the petitioners' families in both *Hazlehurst* and *Snyder* have been willing to make the record of their hearings publicly available. The public will be allowed into the courtroom in each case, although the seating capacity will be limited, due to the size of the available courtrooms.² In addition, in each case, interested parties will be able to download from the Internet both the audio record of the proceeding and the transcript, as was the case during the June hearing. However, the audio record and transcripts will not be available on a day-by-day basis, as was the case with the June hearing, but will instead be available at the conclusion of the entire hearing. (Unfortunately, we will be unable in either case to provide the type of telephonic "listen-in" connection that was available during the June hearing.)

E. The petitioners' additional theories of general causation

As noted previously, the PSC proposes to present *three different* theories of "general causation." The first is the theory that MMR vaccines and thimerosal-containing vaccines can *combine* to cause autism. 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

On June 25, 2007, the PSC filed into the Autism Master File a proposal concerning the timing of the test cases as to the *second* theory, that thimerosal-containing vaccines alone can cause autism. On July 6, 2007, respondent sent a letter containing respondent's own scheduling proposal. (That letter was later filed into the Autism Master File, on August 16, 2007.) The issue was discussed extensively at the status conferences held on July 9, July 20, and September 24, 2007, and we issued an Order describing certain aspects of the schedule on September 27, 2007.

²In each of the two cases, the *petitioners* requested that the hearing be held in a certain area, and we have accommodated those requests. In each case, we obtained the largest available courtroom in the area, but were unable to obtain the type of large courtroom that we were able to secure in Washington, D.C. for the *Cedillo* hearing in June.

Under the procedure and schedule that we have adopted the PSC's second theory, the PSC has already filed into the Autism Master File, on August 28 and September 4, 2007, three *general causation* expert reports. The PSC has also filed, on September 17, 2007, a list of potential test cases. The PSC is scheduled to specifically designate the three test cases, and to file a case-specific expert report in each of those cases, on November 19, 2007. The respondent is scheduled to file respondent's expert reports concerning all three cases on February 25, 2008. An evidentiary hearing, pertaining to 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 is to 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.

F. Recent filings

We note that new autism cases filed during the last several months have been assigned to the docket of the Chief Special Master, Gary Golkiewicz, rather than to the docket of any of the three undersigned special masters. That decision was made by the Chief Special Master in order to ensure that the undersigned can focus our efforts in the next few months on resolving the causation-in-fact issues in the "test cases" now before us. Under this approach, any procedural issues in the newly-filed cases will be addressed by the Chief Special Master. However, this initial assignment does not mean that those cases will necessarily remain on the Chief Special Master's docket to the point of final decision. To the extent that such cases are not resolved on procedural issues, the Chief Special Master may at some future time reassign such cases, for rulings concerning causation-in-fact or other issues.

G. 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 the petition was 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.

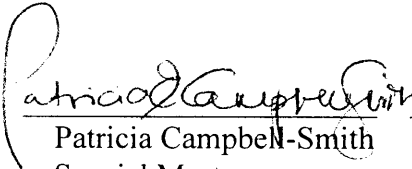
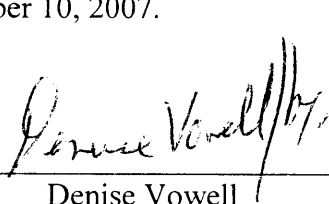
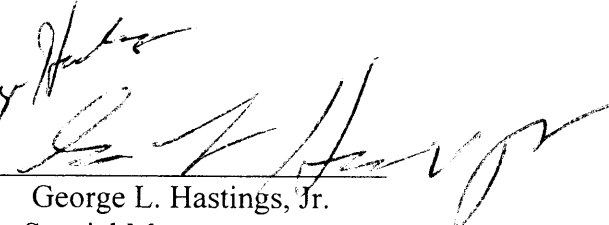
We stress that at this time we will *not* be ordering records to be filed in *all* of the pending autism cases. Rather, the Chief Special Master and counsel are organizing this process in a

deliberate, step-by-step manner. Initially, the PSC is selecting 50 cases in which selected records are to be filed, sufficient to permit a determination with regard to timely filing. We will see how that process proceeds, before issuing orders in any other cases requiring the submission of records. Depending on how the initial process works, we will then move on to require records to be submitted in additional groups of cases, adjusting our procedures if appropriate.

We note that the Chief Special Master and counsel 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.

H. 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 October 10, 2007.

		
Patricia Campbell-Smith Special Master	Denise Vowell Special Master	George L. Hastings, Jr. Special Master